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Supporting Postnatal Women With Opioid Use Disorder Treated With Medication Avoidance Therapy

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by

Lea Ann Quave, MSN

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Abstract

Recent data in 28 U.S. states revealed that opioid use during pregnancy had increased by four times since 2014, going from 1.5 to 6.5 per 1,000 admissions. The use of opioids during pregnancy is dangerous to the mother and developing fetus, greatly increasing the risk for maternal death, miscarriage, and premature birth. The increase in the number of women with opioid abuse disorder (OUD) is reflected by a fivefold increase of infants born with neonatal abstinence syndrome (NAS), a withdrawal syndrome from opioids. Corresponding with U.S. trends, a community hospital in the Texas Gulf Coast region has seen an increase in pregnant women with OUD who are being treated during pregnancy with medical avoidance therapy (MAT). These women are being lost to follow up in the postpartum period, creating an increased risk for relapse and recidivism. The gap in practice is that there is no formal, comprehensive program for postpartum follow-up of women treated for OUD delivering in this facility. The purpose of this DNP project was to utilize a multidisciplinary team to design a set of program guidelines for a comprehensive postnatal follow-up program for women with OUD who were treated with MAT during pregnancy. The theoretical model is the opponent process theory of addition. These guidelines may be used by the maternal-child professionals to decrease the relapse rates of mothers and to improve the maternal-child bonding process.

Keywords: buprenorphine; follow up; methadone; medication assisted treatment; medication avoidance therapy; neonatal abstinence syndrome; opioid use disorder; pregnancy; postpartum; relapse prevention; substance use disorder

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Chapter 1: Introduction

Opioid use disorder (OUD) is found throughout all gender, socioeconomic, and cultural groups across the United States. Also frequently referred to as opioid abuse, opioid dependence or opioid addiction, OUD is an uncontrollable pattern of using opioids without the ability to stop, which results in impaired psychosocial functioning and inability to fulfill normal obligations (Centers for Disease Control and Prevention [CDC], 2019a). Opioid disorder involves illegal drugs such as heroin, illicit use of opioid pain relievers such as morphine and codeine, and the misuse of commonly prescribed opioid pain relievers (POPRs) such as hydrocodone, oxycodone, and codeine (CDC, 2019a). The opioid crisis has been declared a public health emergency by the Secretary of the United States Health and Human Services (HHS) department at the request of President Trump, authorizing aggressive action in the treatment and recovery efforts of OUD (HHS, 2017).

Over two million people were reported to have OUD in 2018 (CDC, 2018b; HHS, 2019). In the same year, 9.9 million people in the United States reported misusing prescription opioids, ranking opioid misuse as one of the top two common forms of substance abuse in the country (Substance Abuse and Mental Health Services Administration [SAMHSA], 2019b). The severity of OUD in the nation has drastically affected mortality rates over the past 18 years. Of the 70,200 plus deaths that occurred due to drug overdose in 2017, over 47,700 resulted from opioid use; this data indicates a six-fold increase over opioid overdose deaths reported in 1999 (CDC, 2018b).

Opioid use in women is rising and has been declared a national epidemic that is detrimental to the country's future. In 2015, 57% of the 2.1 million people in the population with opioid misuse were women (Brogly et al., 2018). Women make up 65% of the prescribed users

for POPRs, with women being 40% more likely than men to develop OUD from persistent use (National Women's Health Network [NWHN], 2018; Pacira Pharmaceuticals, Inc., 2017). Programs for opioid treatment have shifted from having an 80% male-dominated population in the 1960s to a predominately female population reported in 2010 (Krans & Patrick, 2016). In 2010 alone, over 200,000 women sought treatment for OUD through emergency departments (EDs), with a ratio of one POPR related death for every 30 visits (CDC, 2013). From 1999 until 2010, prescription opioid overdose in women increased by 400%, resulting in an average of as many as 18 deaths each day (CDC, 2018b; Lind et al., 2017). A 10.6% increase in opioid overdose-related deaths in women occurred from 2016 to 2017, resulting in over 15,000 deaths (Scholl et al., 2019).

Recent data from 28 states revealed that opioid use during pregnancy had increased by four times since 2014, going from 1.5 to 6.5 per 1,000 admissions (Haight et al., 2018). The actual number of pregnant women in the general population affected by the opioid epidemic is considered much higher since this particular study did not include the 50% of births not covered by Medicaid, the report of illicit opioid use, or births resulting in miscarriage or fetal demise (Haight et al., 2018). The use of opioids during pregnancy is dangerous to the mother and developing fetus, greatly increasing the risk for maternal death, miscarriage, premature birth, congenital birth defects, and other physiological problems for the infant (American College of Obstetricians and Gynecologists [ACOG], 2017; Carter et al., 2019; Park et al., 2012). The increase in the number of women with OUD is reflected by a fivefold increase of infants born with neonatal abstinence syndrome (NAS), a withdrawal syndrome from opioids or opioid-based medical avoidance therapy (MAT) that can cause mild to severe respiratory, central nervous

system, and gastrointestinal distress in newborns (Haight et al., 2018; Logan et al., 2013; McQueen, & Murphy-Oikonen, 2016; Patrick et al., 2015; Wolf et al., 2019).

Pregnancy for women with OUD presents complex medical and psychosocial issues to manage during the pregnancy and to protect the well-being of the fetus. The common treatment for opioid use disorder is outpatient MAT with oral administration of an authorized prescription opioid agonist, partial opioid agonist, or opioid antagonist such as methadone or buprenorphine (Jones et al., 2008; Keough & Fantasia, 2017; Krans & Patrick, 2016; Saia et al., 2016; Shainker et al., 2012). Without continued treatment MAT after pregnancy, the risk of postpartum opioid relapse is extremely high, presenting immediate health risks to the mother and infant and long-term psychosocial issues for mother, infant, family, and society (Park et al., 2012; Saia et al., 2016).

A gap has been identified in the provision of recovery support for postpartum women with opioid use disorder in this community in the Texas Gulf Coast region. A structured, comprehensive interdisciplinary follow-up for mothers during the postpartum period has been proven to reduce the risks of relapse (Forray et al., 2015). This Doctor of Nursing Practice (DNP) nonexperimental project focused on the review of evidence-based literature, professional guidelines, and theoretical models for the design of a comprehensive postpartum program for women with opioid use disorder to reduce the propensity for relapse and improve the quality of care in this population.

The needs of postpartum women with OUD are diverse and require a comprehensive approach that is multidisciplinary in nature; therefore, the postpartum program's design will include the input and review of a group of expert stakeholders. This multidisciplinary group of experts was proposed to include an obstetrician, a pediatric nurse, a social worker, an addiction

specialist, a community health clinic advanced practice nurse who specializes in women's health, the director of the labor and delivery unit and nursing staff at a local hospital, a counselor from the local Woman's Center for Domestic Violence, and a grant writer. The addition of a grant writer was hoped to lend credibility and feasibility to the project's transition into practice.

Statement of the Problem

Corresponding with national trends, a community hospital in the Texas Gulf Coast region has seen an increase in pregnant women with OUD who are being treated during pregnancy with MAT. These women are being lost to follow up in the postpartum period, creating an increased risk for relapse and recidivism. Although continued treatment after pregnancy is needed, the gap in practice is that there is no formal, comprehensive program for postpartum follow-up of women treated for OUD delivering in this facility. In order to meet a national mandate to address the opioid crisis at the local level, a program is necessary to provide holistic care that encompasses the complex physical, psychological, and psychosocial needs of this patient dyad.

Giving birth and assuming a maternal role can be a difficult mental and physical transition for all women; anxiety, exhaustion, feelings of inferiority, and postpartum depression (PPD) are common for all new mothers. The standard postpartum health issues are compounded for women with OUD who had been treated with MAT during pregnancy, as these women are highly susceptible to additional physical, mental, economic, and social problems; furthermore, many of these women have experienced physical or sexual abuse, domestic violence, or traumatic events during their lives (Baldacchino et al., 2014; Beckwith & Burke, 2015; Calhoun et al., 2015; Humbarger et al., 2016; Kelty & Hulse, 2017; Levine & Woodward, 2018; Logan et al., 2013; Maguire et al., 2016; McGlone & Mactier, 2015; McQueen & Murphy-Oikonen,

2016). These historical psychosocial factors increase the risk of worsening preexisting psychological disorders (Niccols et al., 2012).

Additionally, social disparities and biological influences create a propensity for relapse in this population. Homelessness, unemployment, knowledge deficits related to parenting skills, limited access to proper nutrition, lack of transportation, and absent support systems increase feelings of helplessness in postpartum women with OUD (Niccols et al., 2012). Hormonal changes brought on by the return to prepregnancy state can increase the physiological desire for opioids, which may lead to the mother seeking illicit opioids to satisfy addiction cravings (Park et al., 2012). The probability of relapse for these mothers is high; subsequently, the need for continued formal structured care of these mothers is also high.

The development and operation of a formal, comprehensive postnatal program that includes a plan of care for assessment and referral of women to a multidisciplinary support system can improve the woman's physical and mental health and increase the quality of life for the mother-child dyad. Postpartum mothers who participate in follow-up programs for substance abuse which incorporate psychosocial interventions aimed at improving the mother-child relationship have shown more effective parenting skills, fewer symptoms of depression and other physiological disorders, lower rates of possible child abuse, and a more positive report of emotional bonding between mother and child (Niccols et al., 2012). Comprehensive formal follow-up provides opportunities to assess adherence to medical therapy and opioid use relapse in the mother, as well as identifying additional physical, mental, and social problems, which require intervention.

It is important to provide a formal, comprehensive follow-up for postpartum women after medical therapy for opioid use during pregnancy, which includes the continued assessment of the

infant for onset or complications of NAS and developmental delay. Comprehensive care postpartum with a transition to addiction recovery and support for mothers treated with MAT during pregnancy and whose infants may have NAS is an important yet underresearched area. There is a need to utilize current evidence to fill knowledge gaps and expand treatment for postpartum women with OUD and their infants. It is believed that a multistep approach consisting of the review of evidence-based literature, critical appraisal of evidence, and compilation of an evidence to decision (EtD) framework to design a comprehensive formal postnatal program may reduce the propensity for relapse and improve outcomes in this population.

Background

Opioid Use Rates and Prevalence

Opioid use among the American population has increased at alarming rates, raising concerns among public health officials and healthcare providers. Prescription pain relievers and synthetic opioids are the most common drugs of choice. Opioids reduce pain and create a feeling of euphoria that is highly addictive and can quickly lead to OUD, which is defined as "a chronic lifelong disorder with serious potential consequences including disability, relapse, and death" and further described as a "problematic pattern of opioid use leading to problems or distress" (American Psychiatric Association [APA], 2018, para. 8). The disorder has become a health care crisis that affects millions of people nationwide, necessitating the declaration of a national public health emergency requiring urgent attention (CDC, 2019b; HHS, 2017).

In 2014, enough POPRs were legally prescribed to allow every adult in the country to have their own bottle (Wheaton et al., 2014). Over 11 million persons reported using illicit opioids in 2017 (Substance Abuse Center for Behavioral Health Statistics and Quality [CBHSQ],

2018). A six-fold increase in the national rate of deaths from opioid overdose occurred from 1999 to 2017, with 400,000 opioid-associated deaths during this time (CBHSQ, 2018). Overdose from OUD resulted in 47,600 deaths in 2017 alone: an increase of 45.2% from 2016 (CDC, 2018b). In the United States, an average of 130 opioid overdose-related deaths occur daily (CDC, 2018b). In addition to deaths from legally prescribed and illicit opioid overdose, deaths from methadone MAT are attributed to 33% of opioid overdose deaths (Ray et al., 2015; United States Department of Health and Human Services, Centers for Disease Control and Prevention, & Division of Unintentional Injury Prevention [DHHS], 2016).

Opioid Use in Women

The unique biological responses of women make them more susceptible than men to OUD. Body composition, hormones, decreased glomerular filtration rate, and lower metabolism rate increase the time substances take to eliminate from the female body (Legato et al., 2016). Women are more apt to develop a substance use disorder (SUD) in response to emotions, traumatic life events, and stress (Cheng et al., 2016; Meléndez et al., 2012; SAMHSA, 2015b). Many women initiate substance use in response to the pressure of a relationship partner with a substance use disorder, seeing the act as a way to bond with their partner (SAMHSA, 2015b). Opioid misuse is often coupled with codependent tendencies, domestic violence, or other types of abuse (SAMHSA, 2015b). Mental disorders such as anxiety and depression; history of trauma; history of mental, physical, or sexual abuse; addictive behaviors; socioeconomic factors such as poverty, discrimination, level of education, unemployment, and social status; and trouble with law enforcement present risks for substance abuse and challenges with recovery for women (SAMHSA, 2015b). Many women have issues with low self-esteem, self-worth, and self-esteem, which lend to a predisposition to OUD (Currow et al., 2016; DHHS, 2016).

Opioid Use in Women of Reproductive Age

Many women with a substance abuse disorder, including opioid use, are in their prime reproductive years, defined as females age 15 to 44 (SAMHSA, 2018). The number of women of reproductive age (WRA) affected by OUD and subsequent opioid overdose has continued to rise at a disturbing volume. From 2008 to 2012, more than one-fourth of privately insured and close to 40% of Medicaid-insured WRA filled at least one prescription for POPRs each year (Carter et al., 2019; Lind et al., 2017). From 2002 to 2013, the rate of WRA reporting dependence on heroin during the past year increased by 100% (Lind et al., 2017). From 1998 to 2011, OUD in WRA increased by over 120% (Maeda et al., 2014). Of the 200,000 women seeking ED treatment for OUD in 2010, over 119,500 were classified as WRA (CDC, 2018a). In 2017, over 8,000 deaths were recorded from opioid overdose in women in their reproductive years, with over 2,900 of those related to prescription opioid pain relievers (POPRs; Scholl et al., 2019). This trend of increasing deaths parallels reported opioid use in women of this age group, causing major concern for their physical and psychosocial health.

Opioid Use in Pregnancy

Opioid use in pregnant women is found across all ethnic, socioeconomic, and geographical regions. In a study across 46 states, including over 1.1 million antepartum women with Medicaid benefits, 20% had used outpatient POPRs during pregnancy (Desai et al., 2014). Premature deliveries, low birth weight infants, in utero passage of meconium causing respiratory distress, and developmental growth delays are more common in infants of mothers who take opioids during pregnancy, even with short-term or occasional use (ACOG, 2017; Park et al., 2012). Maternal opioid use may alter neurodevelopment of the fetus and lead to autism spectrum disorder and developmental deficits in children (Rubenstein et al., 2019). These infants are also

at risk for other long-term cognitive, neural, and behavioral issues (Baldacchino et al., 2014; Beckwith & Burke, 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; Park et al., 2012).

Treatment with MAT during pregnancy has been found to reduce addictive cravings and curtails several health problems associated with maternal opioid use for mother and fetus during pregnancy and at the time of delivery (Ross et al., 2015; SAMHSA, 2019a, 2019c). Abrupt discontinuation of MAT or sudden withdrawal of opioids during pregnancy are discouraged as these may lead to distress for both the mother and the fetus. Intermittent spikes in opioid levels can cause physical damage to the fetus, as well as low compliance and high risk of relapse in the mother (American Society of Addiction Medicine [ASAM], 2015; Park et al., 2012). Opioids, including common forms of MAT, pass to the fetus during pregnancy through the maternal-fetal circulation; however, adhering to a consistent treatment regime of MAT maintains a steady dose to the fetus and prevents withdrawal symptoms similar to NAS in utero (ASAM, 2015; Park et al., 2012).

Research Organization Demographics

The practice project organization is located in a county on the Texas Gulf Coast region and is a satellite facility of a major educational hospital system in a neighboring county. The project organization site is located in a predominantly rural county having a population of 354,195, with the city where the hospital setting is located having a population of 19,491 (Gulf Coast Center, 2018). The county population's mental health and substance abuse needs are serviced by the Gulf Coast Center for Mental Health, which is located approximately 50 miles from the project organization site (Texas Health and Human Services, 2019). There is no local

governmental county health department program located within the immediate community. The community does have several inpatient and outpatient substance abuse facilities, but none treat the specific needs of postpartum women with OUD, nor do they cater to the needs of women in general.

Though the rate of drug use in the county may be lower than some of the more populous counties in Texas, the problem affects many in the community each year. During 2016, 58.8 opioid prescriptions per 100 persons were written for persons within the county (CDC, 2017). In the same year, emergency medical professionals at the setting locality responded to 92 cases of opioid overdoses, with an opioid reversal agent being administered in 12 of the cases (Gulf Coast Center, 2018). During 2017, there were 1.08 POPR prescriptions written for each Medicaid patient and 39 overdose deaths recorded in the county resulting in a rate of 10.8 deaths for every 100,000 persons (Foundation for AIDS Research [AMFAR], 2019). Due to being located in close proximity to the gulf coast and the border of Mexico, the county has been identified by the Drug Enforcement Agency (DEA) as one of 19 counties in Texas with the with the designation of a High Intensity Drug Trafficking Area (HIDTA; Prevention Resource Center 6, 2017).

Need for the Project

There are several gaps in the provision of OUD services in this area to postpartum women as well as the general population that fall in line with the findings of a report by the Council on Recovery (Prevention Resource Center 6, 2017). The council found that rural counties, especially those found along the coastal border, lacked sufficient providers to service the population's substance abuse needs (Prevention Resource Center 6, 2017). Because of the low socioeconomic status of many of the residents in the area, many persons with substance abuse issues lack financial resources, are uninsured, and do not have adequate transportation to

travel to the Gulf Coast Center (Prevention Resource Center 6, 2017). Despite the need for services in the county, there are no adequate resources or programs to meet the financial and logistical needs of the residents.

The main branch of the academic hospital organization in the neighboring county has been on the forefront of addressing the opioid crisis by implementing programs to decrease addiction and misuse risks. Examples of programs are a physician-led initiative to decrease overprescribing of POPRs, requiring physicians to become more accountable for the stewardship of opioid use, continuing education programs for providers and those who administer opioids on current guidelines, education on alternative treatments for pain such as acupuncture, pain contracts that outline patient and provider responsibilities for pain control, and implementing technology in the electronic health record (EHR) to access the state POPR prescribing database before prescribing opioids (Clifford, 2018). The local facility setting for the practice problem has benefitted from these initiatives. The organization's culture is open to exploring new methods and practice initiatives aimed at controlling the adverse effects of OUD on the community.

Accreditation and Certification

An opioid treatment program (OTP) is defined as a medical practice or formal program that manages the treatment of OUD by prescribing or dispensing MAT; these programs are under strict federal regulations requiring certification by SAMHSA, accreditation with the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), and registration with the Drug Enforcement Administration (DEA; SAMHSA, 2015a). The first set of guidelines, *Federal Guidelines for Opioid Treatment Programs,* were published by SAMHSA in 2001 after consensus by an expert panel convened to address the rising opioid crisis; an update to the guidelines was published in 2007 and again in 2015 (SAMHSA, 2015a). The latest version of the

guidelines addresses the most current trends in health care, such as technological advances (electronic health record, telemedicine, electronic device digital therapy); drug monitoring programs; nursing scope of practice; and a model for recovery-oriented patient-centered care (SAMHSA, 2015a). As outlined by SAMHSA, the comprehensive guidelines can serve as a directive to contribute to the design of a program for postpartum care for the mother-child dyad.

Since this evidence-based practice program did not include prescribing or dispensing MAT, it was not considered an OTP under federal standards and is not held to the requirements for certification, accreditation, or registration with the aforementioned entities. However, the facility chosen for the setting of this practice problem meets the specification of a qualified practice setting according to the following federal guidelines: (a) provides 24-hour emergency services; (b) provides case management services to address behavioral health and psychosocial follow-up needs; (c) utilizes health information technology to record in an EHR and coordinate care; (d) is registered with the state prescription drug monitoring program (PDMP); and (e) participates in third-party billing, private and federal insurance, and self-pay for coverage of services (Electronic Code of Federal Regulations [e-CFR], 2020). The practice site is accredited with JCAHO and multiple other federal and health care organizations.

Purpose of the Project

With an increase in the number of pregnant women at a community hospital in the Texas Gulf Coast region presenting with OUD and treatment with MAT during pregnancy, a need has been identified to reframe interventions to improve follow-up in the postpartum period to decrease the risk for recidivism and relapse. The purpose of this scholarly Doctor of Nursing Practice (DNP) nonexperimental prospective exploratory project was to utilize best evidence-based literature, professional guidelines, and theoretical models for the design of a

comprehensive postnatal program for this population. The program design uses a multistepped Delphi technique data collection format beginning with a systematic literature review from quantitative and qualitative evidence-based literature to format a set of formal guidelines for the care of a vulnerable population. This program can provide a structure and process for implementing best practice clinical guidelines for the management and support of the postpartum mother-child dyad.

The evidence was presented to a multidisciplinary team consisting of an obstetrician, a pediatric nurse specialist, a social worker, an addiction specialist, a community health clinic nurse, nursing staff in the labor and delivery unit of a local hospital, and representatives from local community agencies that offer recovery and parenting services for input into the design of a comprehensive postnatal program. A structured multidisciplinary holistic approach to postnatal follow-up can improve the spiritual, mental, physical, and social well-being of women with OUD (Kerlin, 2017; SAMHSA, 2018). The project's goal was to create a formal, comprehensive multidisciplinary follow-up program for postnatal women who were treated with MAT during pregnancy that will address the physical, psychosocial, and environmental needs of the mother-child dyad and improve outcomes for this population.

Significance of the Problem

Significance to Postpartum Women With OUD

Many of these women have experienced childhood and adult trauma, as well as lifelong adversities that have played a hand in their propensity for OUD and can negatively impact recovery and ultimately lead to relapse. During the postpartum period, the propensity for recidivism to opioid use is increased for new mothers treated with MAT during pregnancy due to the discontinuation of needed services. The initial physiological and psychosocial factors that

lead to OUD still exist, combined with the stress of motherhood, feelings of guilt resulting from social stigmas, and domestic disparities such as homelessness, poverty, and partner violence (Cheng et al., 2016; SAMHSA, 2018; Schiff et al., 2018). A formal, comprehensive follow-up program including treatment with MAT and the availability of essential services will help this population navigate through the hormonal changes of the postpartum period, care of an infant that may be unhealthy due to NAT, increased opioid cravings, psychosocial disparities, and the risk of postpartum depression on their own (Schiff et al., 2018). The extra medical treatment, nursing care, support, and education a follow-up program would provide could decrease the risk for relapse for the postpartum women treated for OUD during pregnancy.

Overdose during the first year after giving birth is a major contributor to maternal pregnancy associated death (Schiff et al., 2018). According to the Maternal Mortality and Morbidity Task Force, in 2017, 58% of all drug-related maternal deaths in Texas that occurred during the first year postpartum were the result of opioid overdose (Texas Department of State Health Services, 2018). Due to the increased possibility of preexisting mental health issues coupled with the propensity for postpartum depression in women with OUD, frequent screening for depression, suicidal ideations, and signs of relapse should be incorporated into postpartum care within the first year after birth (SAMHSA, 2018). Close follow up can reduce the high overdose mortality rate for these women.

Significance to the Community

Opioid abuse has devastating effects within the community and presents a health crisis that needs to be valiantly met with individualized programs specifically aligned to the community resources. Early intervention is needed to nurture the development of a caring relationship within the mother-child dyad and to build positive parenting skills that empower

women with OUD to develop safe, stable environments in which to raise their children and reach their full potential in the community. Many children of women with OUD become the responsibility of the community and governmental agencies. Exposure to parental OUD during the formative years can put children at risk for multiple health issues, learning disabilities, and an increased propensity for future substance use disorders (Widom & Brzustowicz, 2006). This program can help to meet the needs of communities in the overall effort to reduce opioid dependence in the maternal population, which will help to stop the cycle of opioid misuse and decrease the number of children placed in foster care.

Mothers struggling with OUD often do not partake in optimal self-care activities, nor do they have the resources to take care of themselves, their responsibilities, or their children. They can find it hard to function in daily life, with family, at work, and in the community. Often these women face life circumstances that have been altered by loss of employment, loss of home, loss of family support, and loss of access to the same level of medical services available during pregnancy. These women are often unable to form meaningful personal connections and are accustomed to living with a string of damaged relationships. Changing an addictive behavior is challenging and becomes a lifelong effort; so many aspects of life must be changed at once, making it difficult not to fall back into old habits (National Institute of Drug Abuse, 2017). This population is often seen as weak; however, they can be a very resilient group of women. They have usually overcome many obstacles and adversities within their lifetime and can be highly motivated if given the right tools and support.

Significance to Maternal and Child Nursing

A comprehensive follow-up program for postnatal women with OUD is important to ensure that women and children affected by this disorder receive respectful and empathetic care

by nurses trained to recognize OUD as an addictive disease and not a social stigma. The outcomes of a structured program for postpartum women with OUD are congruent with the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) position and standards for women with substance use disorder during pregnancy and the postpartum period. It is AWHONN's position to (a) not support the "incarceration or other punitive legal actions against women" during "pregnancy and the postpartum period"; (b) screen women initially and periodically for SUD during and after pregnancy with "a validated tool"; and (c) provide MAT and "family focused" care that is "non-stigmatizing" (Association of Women's Health, Obstetric and Neonatal Nurses [AWHONN)], 2019, para. 1). Misconceptions and outdated conventions about OUD during pregnancy and postpartum can impede the quality of nursing care.

It has not been uncommon for substance use by pregnant women and mothers of young children to be associated with bias and prejudice, projecting shame and guilt on those who struggle with OUD. Supportive practitioners are critical for the successful recovery and healing of postnatal women with OUD. Following a plan of care specifically designed for postpartum women with OUD can guide nurses in a structured format that increases their knowledge and confidence in providing evidenced-based care for these women. A comprehensive follow-up program managed by specially trained nurses can address opioid use recovery with a compassionate and understanding approach that fosters a culture of support and hope and alleviates any sense of moral failure for the mother.

Evidence-based assessment and treatment for NAS can help to decrease the morbidity and mortality risks for the infants born to women with OUD during the postpartum period. Every 60 minutes, a child is born with NAS in the United States (Patrick et al., 2015). Infants with NAS, or those with a risk of developing NAS, should be seen earlier and more frequently during

the postnatal period to monitor for complications. Medical costs and resources for NAS take away from funds and resources that could be used to treat other medical conditions. In 2016, the cost of care for infants with NAS in Texas was over $66 million, with 74% of the costs funded by public insurance (Myers, 2018).

Subsequent early pregnancy is a risk for women treated with MAT for OUD during pregnancy and present with an additional set of complications for both mother and infant. Contraceptive methods are usually discussed during the traditional six-week postpartum follow-up visit with the obstetrician; however, evidence has shown that only 43.8% of women with OUD return for this visit (Parlier et al., 2014). The incidence of unintended pregnancy in women with OUD is up to 80% higher during the first three months after delivery than that of women without OUD (ACOG, 2017). Women are advised to abstain from sexual intercourse during the immediate postpartum period; many women with OUD go home to an environment that makes it difficult to abstain.

It is common for these women to engage in sexual intercourse prematurely, leading to a subsequent pregnancy (SAMHSA, 2015b). Early conception after birth can lead to poor maternal and neonatal outcomes. Low birth weight, preterm birth, and infant death are associated with short interval pregnancy (Ahrens et al., 2018). The risks for maternal complications, such as gestational diabetes and preeclampsia, increase with short interval successive pregnancy (Hanley et al., 2017). Education on contraceptive options and usage provided during early follow-up before the traditional six-week postpartum visit can decrease the incidence of unintended short interval pregnancy.

Significance to the Literature

The rates of women with OUD during pregnancy and the postpartum period are continuing to increase, creating a need for further evidence-based literature and models of recovery that support the specific needs of this population of women (Kerlin, 2017; SAMHSA, 2015b). There are currently several innovative programs in conception for women with OUD, but there is a need for more programs that incorporate the complex mix of sociocultural, environmental, spiritual, physical, and psychosocial aspects of OUD in a holistic approach that reduces the risks of relapse and builds the self-respect of these vulnerable women. Existing models of care and relapse prevention should be consistently evaluated for effectiveness and modified for increased success (SAMHSA, 2017).

Nature of the Project

This was a nonexperimental multistep prospective exploratory program design project utilizing the Delphi rounds method of expert stakeholder input for data collection. The purpose of this scholarly DNP project was to utilize the best evidence-based literature, professional guidelines, theoretical models, and review combined with input from an expert panel of stakeholders for the design of a comprehensive program for postnatal women with OUD. The project's goal was to create a structured multidisciplinary holistic approach to postnatal follow-up to improve the mental, physical, and social well-being of women with OUD while decreasing the risk of relapse and improve the quality of the mother-child dyad. The project will set the foundation for advancing the art and science of nursing care for this population.

The project began with a systematic thematic literature review from evidence-based practice literature and professional and government agency guidelines. A critique of the reviewed literature was completed using the Grading of Recommendations Assessment,

Development, and Evaluation (GRADE) system of appraisal. The GRADE Evidence to Decision (EtD) framework was used to synthesize the evidence and form recommendations for a comprehensive postnatal follow-up program for women with OUD who were treated with MAT during pregnancy. The compilation of evidence and recommendations was to be presented to a panel of interdisciplinary stakeholders at a community hospital in the Texas Gulf Coast region that has seen an increase in pregnant women with OUD who are being treated during pregnancy for their input and consensus.

The Delphi method is a process of gaining consensus in practice guidelines or policy through review and communication sessions held between members of an expert stakeholder panel (Brady, 2015). Following the Delphi method for guideline consensus, this project used a five-step process: (a) discover evidence-based practice interventions through a systematic review and grading of evidence; (b) formation of an expert stakeholder panel; (c) surveying the panel for review, suggestive input, and consensus of the evidence; (d) formation of a formal set of guidelines; and (e) a second round of review and consensus from the expert panel. This expert opinion will be integrated into the formation of a formal program plan that includes the structure, the evidence-based process guidelines, proposed formative and summative goals and milestones, and a proposed budget. Theoretical models and currently operating recovery programs for mothers at risk will be considered for guidance in formatting the guidelines. The Appraisal of Guidelines Research and Evaluation (AGREE) II is used as a checklist by the interdisciplinary panel to ensure the credibility of the final set of guidelines. It is hoped that this plan can be presented to funding agencies to establish this program in the community.

Question Guiding the Inquiry (PICOT Question)

The question guiding this program design project is as follows: Will an interprofessional team be able to develop clinical practice guidelines for a program to follow women treated for opioid use disorder during pregnancy with medication avoidance therapy after birth? These guidelines could be used to construct an appropriate 12-month follow-up program to decrease the rates of relapse and promote the maternal-child bonding process. A further description of each of the elements of the question guiding the inquiry is as follows:

P (population): An expert panel of stakeholders that hold an interest in the outcomes of postpartum adult women with OUD who have been treated with MAT during pregnancy and their infants that were delivered in the same local hospital of a community on the Texas Gulf Coast.

I (intervention and exposure): Using the Delphi mythology of guideline consensus to perform a systematic literature review of best evidence-based literature, professional guidelines, and theoretical models; analyzing the results of the review with the GRADE appraisal of evidence method; transferring the findings to an EtD framework to determine best recommendations for interventions; developing formal guidelines using the PWOUD Guideline tool; approval of an interdisciplinary expert panel of stakeholders having an interest in the care of women with OUD that have been treated with MAT during pregnancy. Stakeholder members include an obstetrician, a pediatric nurse, a social worker, an addiction specialist, a community health clinic advanced practice nurse who specializes in women's health, the director of the labor and delivery unit and nursing staff at a local hospital, a counselor from the local Woman's Center for Domestic Violence, and a grant writer.

C (comparison or control): There is no comparison or control for this guiding question. A comparison or control may not be relevant in a question about an outcome that is applicable to a therapy, deeper meaning, or the prognosis of a plan (Fineout-Overholt & Johnston, 2005).

O (outcome): Result in an approved formal structured set of guidelines outlining a comprehensive follow-up program that provides management and support for postnatal women with OUD who have been treated with MAT during pregnancy that can improve the quality of care and outcomes for the mother-child dyad.

T (time): The period for completing the program design project is five months. Performing a Delphi method guideline consensus to perform a systematic literature review of best evidence-based literature, professional guidelines, and theoretical models, and using the GRADE method of appraisal of evidence with an EtD framework to develop a set of guidelines based on criteria from the PWOUD Guideline checklist that has been approved by an interdisciplinary expert panel of stakeholders will result in content consensus and approval of a formal structured set of guidelines outlining a comprehensive follow-up program that provides management and support for postnatal women with OUD in a community on the Texas Gulf Coast that have been treated with MAT during pregnancy.

Theoretical Framework

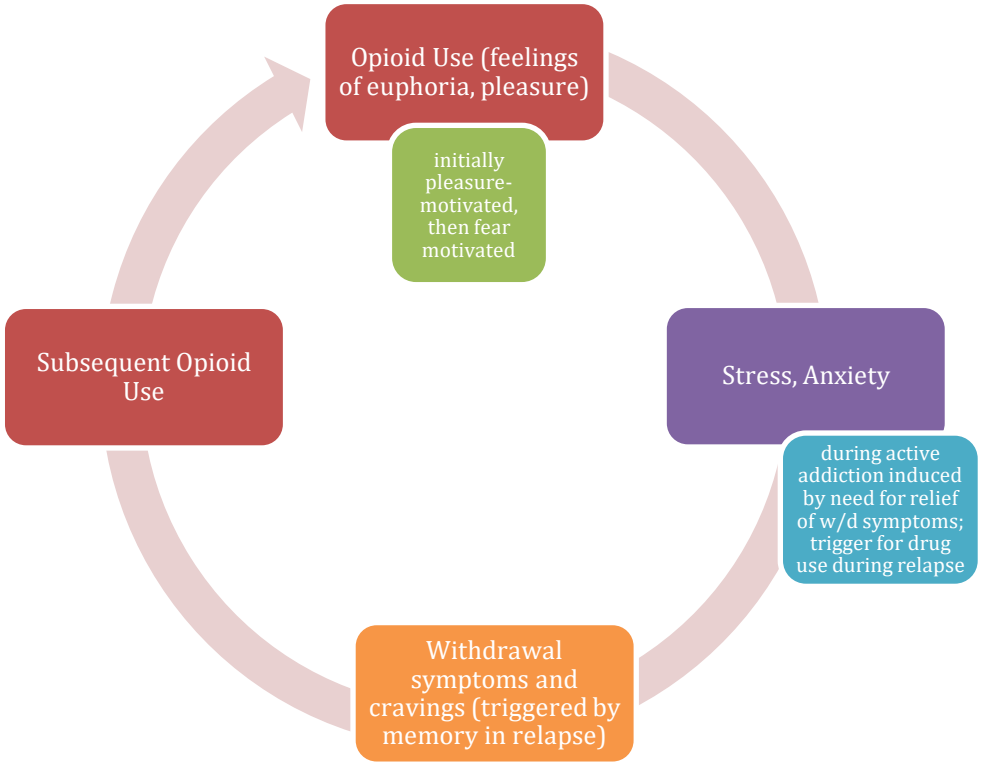
The theoretical framework of the opponent process theory (OPT) can be applied to the emotional and motivational aspects of OUD. The OPT presents that persons who are addicted to or misuse drugs have a reduced feeling of fear that negative results will occur if they abuse medications; instead, fear is replaced by a feeling of relief or reward (Koob, 2020). Driven by emotions and the motivation to avoid negative side effects, the person with OUD continues to abuse opioids in an effort to reduce withdrawal symptoms and excessive cravings (Koob, 2020).

During the initial phases of OUD, the motivation for using opioids is to produce feelings of enjoyment and euphoria; however, these feelings are soon replaced by negative withdrawal symptoms when the person is unable to use additional doses of opioids. At this point, the motivation for using opioids is driven by the need to prevent negative experiences rather than to produce a positive experience.

During periods of withdrawal symptoms and intense cravings, the individual experiences high levels of anxiety, as well as increased physical and emotional stress (Koob, 2020). This cycle of stress and relief-seeking behavior leads to a lack of motivation to stop abusing opioids. If a person does become sober, they maintain stress-induced memory that can trigger relapse when faced with bouts of anxiety or stressful situations (Koob, 2020). It is important to provide stress management, coping skills, and positive reinforcement to prevent the individual with OUD from relapse. The OPT framework (see Figure 1) can be used to guide the development of a formal structured set of guidelines outlining a comprehensive follow-up program that provides management and support for postnatal women with OUD and prevent them from relapse and recidivism.

Figure 1

Theoretical Framework for Opponent Process Theory



Operational Definitions

Buprenorphine. A medication therapy for opioid use that mimics the effects of opioid medications without creating increased cravings; this medication can be self-administered with an authorized prescription (SAMHSA, 2019a).

Medication avoidance therapy. A type of therapy for OUD that includes the use of medications such as methadone and buprenorphine to assist with the withdrawal from opioids and the management of cravings; this type of therapy is usually prescribed in conjunction with counseling (Koehl et al., 2019).

Methadone. A synthetic medication treatment used to treat OUD by blocking the effects of opioids, thus reducing cravings and withdrawal symptoms; this medication must be administered through a highly regulated physician clinical setting (SAMHSA, 2019c).

Mother-child dyad. The coupling of the mother and the child into a single patient care unit based on the dependent relationship of the mother to the child and the child to the mother (Romanowicz et al., 2019).

Neonatal abstinence syndrome (NAS). A disorder that can present in infants of mothers with OUD derived from in utero exposure to opioids or medication treatment for OUD causing severe gastrointestinal and neurological symptoms; NAS generally necessitates intensive medical care for the infant and can result in permanent health issues **(**Kocherlakota, 2014).

Opioid use disorder (OUD). A repeated pattern of behavior characterized as a strong craving for opioids and a loss of control over the number of opioids taken, leading to social problems, risky behaviors, increased tolerance, and withdrawal when opioids are not taken (APA, 2018).

Opioids. A medication that reduces pain and creates a sensation of euphoria by binding to the stimulating reward pathways in the brain and spinal cord; opioids consist of legal prescription medications such as oxycodone, hydrocodone, fentanyl, and morphine, and illegal drugs such as heroin (Hawk et al., 2015).

Scope and Limitations

The structured follow-up program for pregnant women with OUD who were treated with MAT during pregnancy will help guide the health care team providing long-term recovery care to a set of women delivering at a local teaching hospital. The hospital is a smaller branch of a major medical and nursing teaching hospital on the Texas Gulf Coast; the local setting is one of

three community hospitals in the south region of the county and is the primary facility providing care to the underserved and indigent population. The hospital offered a combination of MAT and perinatal care through a community clinic up until July of 2019, at which time the obstetrician in practice at the clinic met with an untimely death. The hospital has continued to provide delivery service to this specialized population of women; however, treatment with MAT was not continued through the hospital. The patients of this particular clinic were divided between physicians from the main campus of the hospital organization.

Members of the health care team will include nurses in the labor and delivery unit who provide immediate postpartum care and discharge for the designated patient population, nurses within the community health department, the hospital's women and children's clinic, obstetrician and pediatrician's office, addiction specialists, and other involved members of involved social and community services. Consultation and input during the program design were sought from individuals and organizations that have contributed to the design and development of similar projects in other communities. The project covers the review and synopsis of peer-reviewed literature written from 2014 to 2019, current addiction and women's health professional organization guidelines, and currently in-service evidence-based practice models. A review of the evidence was presented for further evaluation and critique by an expert committee to direct the writing of a set of guidelines for a structured follow-up program. The committee met in the conference room provided by the designated community hospital and through virtual conferencing due to COVID-19 restrictions.

The actual final program was not implemented within the context of this DNP project but will serve as the groundwork for a pilot program within the hospital and a grant proposal to commence a formal program within the community. Prospective committee members were

excluded from participation in the health care team if they do not currently provide care in the labor and delivery unit of the designated hospital, do not practice in the obstetrics, pediatric, or addiction health care fields, or do not participate in the provision of social or community services in the coverage area of the designated hospital facility.

Constraints related to the health care aspect of the project include (a) a small community setting with a limited population of health care, social, and community services professionals to solicit as committee members; (b) a nursing staff at the hospital that is not experienced with the integration of care for opioid use into their normal delivery and discharge practice; and (c) the recent death of the primary physician providing both obstetrical care and MAT as a combined practice for the targeted population. Active recruitment for an alternative physician is in progress. The busy schedules of the other professionals on the health care review team may interfere with maintaining a consistent participation agenda throughout the review process. A plan to provide access to Delphi rounds via online format will be considered during project implementation. The funds for the projected budget, including compensation for professionals to attend meetings, may be more than is available to the DNP student; however, an online format may reduce the cost of project implementation.

Chapter Summary

The incidence of OUD across the nation is an increasing problem. Especially troubling is the rising rate of women presenting with OUD during pregnancy. The standard treatment for OUD during pregnancy is MAT with methadone or buprenorphine, which curb cravings for the mother and reduce life-threatening withdrawal symptoms for both the mother and fetus. As with opioid use, MAT leads to the risk of a NAS for the infant; NAS is a dangerous complication that can result in intensive care, life-long physical and neurological damage, or death for the infant.

Postnatal care of the mother should include the continuation of MAT to reduce the risk of relapse to the use of illicit opioids. In a small community on the Texas Gulf Coast, there has been found to be a gap in the transition of care during the postnatal period for women with OUD who were treated with MAT during pregnancy. There is no formal, comprehensive program to follow up with the mother-child dyad to monitor the infant for NAS, continue MAT for the mother, or address the many psychosocial disparities often present.

The purpose of this DNP Delphi method nonexperimental project using an integrative thematic literature review was to compile best practice evidence from scholarly sources and professional and government organizations into an EtD framework to be appraised by an expert panel and used to create a guideline for a formal, comprehensive multidisciplinary follow-up program for postnatal women who were treated with MAT for OUD during pregnancy. This nonexperimental program design project will help to guide nursing professionals in the care of postnatal women with OUD and improve the quality of the mother-child dyad.

Chapter 2: Literature Review

Corresponding with national trends, a community hospital in the Texas Gulf Coast region has seen an increase in pregnant women with OUD who are being treated during pregnancy with medical avoidance therapy. These women are being lost to follow up in the postpartum period, creating an increased risk for relapse and recidivism. Although continued treatment after pregnancy is needed, the gap in practice is that there is no formal program for postpartum follow-up of women treated for OUD who have delivered in this facility. The purpose of this DNP project is to design a set of program guidelines for a comprehensive postnatal follow-up program for women with OUD who were treated with MAT during pregnancy.

The research question addressed in the project was, Will an interprofessional team be able to develop clinical practice guidelines for a program to follow women treated for opioid use disorder during pregnancy with medication avoidance therapy after birth? These guidelines could be used to construct an appropriate 12-month follow-up program to decrease the rates of relapse and promote the maternal-child bonding process.

This project was a clinical practice guideline design format consisting of a systematic review of best practice evidence-based literature, appraisal of the evidence, transferring the evidence to recommendations, presenting the recommendations to an expert panel of inter-disciplinary stakeholders for critique, developing a set of formal guidelines, and final presentation of the guidelines for critique and approval from the stakeholders. This chapter describes the evidence-based practice search methodology to identify relevant concepts to further understand opioid use in pregnant and postnatal women and the particular needs of this population. Gaps in knowledge are identified based on what is known from current literature. Furthermore, fundamental and conceptual theory to guide the practice design project isdiscussed.

Search

To present a comprehensive overview of opioid use in pregnant and postpartum women and the specific needs of the mother-infant patient dyad, a literature review was conducted to explore the concepts surrounding this practice problem. This review contained an analysis of qualitative and quantitative studies that contributed to what is known about the various aspects of OUD in pregnant and postpartum women and the issues contributing to the propensity for relapse. An Internet search was conducted for relevant literature from the nursing databases at the Margaret and Herman Brown Library at Abilene Christian University (ACU), which is comprised of the following databases: CINAHL, Health Source: Nursing/Academic, and MEDLINE. Other databases provided through the same library resource were also searched, such as Academic Search Complete, Alternative Health Watch, ProQuest Nursing and Allied Health Database, PubMed, Science Direct, Social Work Abstracts, and SAGE Research Methods.

In addition to the ACU library, additional Internet searches provided background and general knowledge to support the primary problem. The results of the Internet searches included the Cochrane database and various professional and government organizations, including the American College of Obstetricians and Gynecologists; American Psychiatric Association; American Society of Addiction Medicine; Association of Women's Health, Obstetric and Neonatal Nurses; Centers for Disease Control and Prevention; National Academies of Sciences, Engineering, and Medicine; National Committee for Quality Assurance; National Institute of Drug Abuse; Substance Abuse Center for Behavioral Health Statistics and Quality; Substance Abuse and Mental Health Services Administration; Texas Department of State Health Services; and the United States Department of Health and Human Services. The professional and government organizations provided statistical information and guidelines for care of women with

substance use disorders and their children. Over 300 full-text peer-reviewed English-only articles published between 2012 and 2019 were reviewed; 23 were selected to contribute to the content of this DNP project.

Theoretical Framework

Addiction theory appropriately explains the physical and psychological aspects of substance abuse, including OUD. Several addiction theories can be applied to the exploration and explanation of addiction, leading to a better understanding when planning care for the postpartum woman with OUD. After reviewing various theories, the opponent process theory (OPT) was chosen to explain the emotional and motivational struggle with addiction and relapse that this population faces as they navigate through the fourth trimester. There has been much debate in the neuroscience and psychological disciplines to determine if OUD and addiction in general, is a pathological disorder of the brain or a psychological illness (Farisco et al., 2018). What is known is that "addiction can be described as a chronically relapsing brain disorder which shares the same brain pathways of reward systems" (Farisco et al., 2018, p. 1).

The premise of OPT is based on the cycle of transforming fear from negative consequences of opioid use to the satisfaction felt by the reward system that is achieved when opioids are used in the presence of stressful situations (Koob, 2020). Koob (2020) stated, "Negative emotional states set up a powerful motivational state for relapse" (p. 45). Compulsive reactions caused by emotions evoked from stressful situations lead to relapse to opioid use, driven by decreased self-control, impaired reasoning, and the inability to effectively make decisions (Farisco et al., 2018). Stress increases cravings for reward satisfaction and relief, feeding the cycle of addiction and decreasing the fear of negative consequences (Farisco et al., 2018; Koob, 2020).

When applying OPT to the postpartum women with OUD during the fourth trimester, the various psychosocial dynamics associated with new motherhood, caring for a child with NAS, and attempting to maintain sobriety in a high-stakes environment provide stressful situations that lead to emotional distress, compulsive cravings, and tendency to find relief through opioid use. Although the postpartum woman with OUD who was treated with MAT during pregnancy may be motivated to refrain from the negative effects of drug use on herself and unborn child, stressful situations may trigger a need for relief and a positive experience (Koob, 2020). Developing a program for this population that addresses the need to reduce disparities and stressful environmental stimuli can positively influence the cycle of transforming fear to reward and reducing the tendency to relapse.

Review of Literature

Treatment of OUD in Pregnancy

Methadone and buprenorphine are medications that are commonly used to treat OUD and manage withdrawal symptoms. Methadone, a mu-opioid receptor agonist that alters the interpretation of pain, has been widely prescribed to decrease withdrawal symptoms and cravings during recovery from opioid misuse, although some addictive feelings of euphoria usually remain until the patient becomes resistant to the effects (APA, 2018; ASAM, 2015; Ross et al., 2015; SAMHSA, 2019c). Buprenorphine is an opioid derivative with mixed agonist-antagonist effects also used for opioid dependency and to manage withdrawal symptoms (ASAM, 2015). Methadone is provided in pill form for daily dispensation at highly regulated clinics due to strict monitoring requirements; buprenorphine is prescribed weekly in pill form and can be filled at a pharmacy (APA, 2018; ASAM, 2015). Both medications are approved for the treatment of OUD

in pregnancy; however, buprenorphine has been found to have fewer side effects for the mother and infant (Carter et al., 2019).

It is recommended that women continue with a consistently monitored MAT regime throughout the entirety of the pregnancy to maintain uniform drug levels in maternal and fetal circulation, decrease opioid cravings in the mother, and decrease adverse health outcomes in the fetus (Baldacchino et al., 2014; Kelty & Hulse, 2017; Levine & Woodward, 2018; Park et al., 2012). Withdrawal symptoms of opioid or MAT can begin as soon as six to 12 hours after the last opioid dose, causing extreme sympathetic nervous system stimulation in the mother and fetus (ASAM, 2015; Denenberg & Curtiss, 2016). The health risks to the fetus associated with opioid use during maternal relapse outweigh the potential health risks to the fetus from methadone or buprenorphine therapy (ASAM, 2015).

During the third trimester of pregnancy, the increased blood circulation and metabolism of the maternal body lead to lower levels of methadone in plasma and increased MAT clearance times (ASAM, 2015). Dosage levels are generally increased until after delivery to maintain therapeutic levels. Postpartum MAT must be continued, adjusting medication and dosage as needed to reflect the retrogressively changing metabolism of the mother (ASAM, 2015; Park et al., 2012).

Neonatal Abstinence Syndrome (NAS)

In addition to the negative impact OUD has on the physical health of the mother, maternal opioid use before, during, and after pregnancy can cause devastating health outcomes for the fetus. During the withdrawal period, infants with NAS can display a myriad of symptoms, which may include extreme and spontaneous high-pitch crying, tremors, hyperactive reflexes, and an inability to sleep (Haight et al., 2018; Logan et al., 2013; McQueen & Murphy-Oikonen,

2016; Patrick et al., 2015; Wolf et al., 2019). Additional symptoms include decreased desire to feed, poor sucking reflex, skin mottling, extreme movements, convulsions, fever, excessive yawning, difficulty breathing, increased respirations and heart rate, vomiting, and diarrhea (Haight et al., 2018; Logan et al., 2013; McQueen & Murphy-Oikonen, 2016; Patrick et al., 2015; Wolf et al., 2019). A higher rate of infants born with gastroschisis, a disorder characterized by contents of the abdomen protruding outside of the abdominal wall at birth, has been associated with counties that had higher POPR use in WRA (CDC, 2020; Short et al., 2019). Neonatal abstinence syndrome symptoms occur in up to 95% of infants born to women who take opioids or are treated with MAT during pregnancy, with up to 50% of cases necessitating prolonged medical treatment, including admission to the neonatal intensive care unit (NICU; Baldacchino et al., 2014; Gawronski et al., 2014; Kelty & Hulse, 2017; Maguire et al., 2016). This results in separation of the mother and infant during the important postnatal bonding period and psychological distress for mothers observing infant suffering (Park et al., 2012).

Manifestations of NAS can present with a wide range of symptoms that frequently occur within the first 72 hours after birth, lasting anywhere from a few days to several weeks. However, the infant may not show signs and symptoms for up to two weeks after birth (ACOG, 2017; Logan et al., 2013). Treatment for NAS increases the use of health care resources and financial costs associated with newborn care, which consists of strict monitoring and management of symptoms by medical staff, most always requiring admission to the NICU (Logan et al., 2013). Infants exposed to opioids in utero should be assessed for symptoms, or complications, of NAS for an extended two-week period following discharge from the delivering facility. Mothers who have returned to opioid use may not have the essential knowledge to recognize complications in the newborn or new-onset NAS.

Unique Needs of Postnatal Women

Traditionally, the postpartum care period has been defined as the hour after birth through the first six to eight weeks after delivery. The emerging consensus is postpartum care should continue to include the first year after birth, with reference to this longer postpartum period as the fourth trimester (ACOG, 2018). Comprehensive care during the fourth trimester should address the physical and psychological changes the woman experiences during this time and should include emotional, sexual, and physical recovery; management of health and chronic disease; contraception and family planning; and screening for depression, mood disorders, sleep disturbances, and issues caring for the infant (ACOG, 2018, Haran et al., 2014; Suplee et al., 2014; Thiel de Bocanegra et al., 2013).

Women and men differ in the progression to OUD both physiologically and psychologically. More women than men use prescription opioids to ease chronic pain for longer timeframes, in stronger doses, and more frequent episodes (Bawor et al., 2015). The rate of OUD from prescription opioids is subsequently higher in women than in men; furthermore, the burdens created by the disorder are felt more strongly in women (Bawor et al., 2015). Women experience more health issues and psychosocial problems related to opioid use than do men (Bawor et al., 2015). Gender-specific treatments are needed to address the increased physical, psychological, and social implications of OUD in women (Bawor et al., 2015). Barbosa-Leiker et al. (2018) found that more women than men had been previously treated for OUD, entered treatment for OUD earlier, reported using opioids for fewer years, were less likely to actively participate in treatment, and had lower retention. Additionally, more women than men with OUD had been victims of sexual or physical abuse and reported previous suicide attempts (Barbosa-Leiker et al., 2018).

Role Transition Anxiety

Anxiety accompanying the transition associated with becoming a new mother can be overwhelming for any woman but is especially troubling for postnatal women with OUD. During pregnancy and the postnatal period, women with OUD have a propensity for anxiety and other mental health disorders, with over 64% of women in this population found to have one or more disorders according to a recent study; 40% were evaluated to have anxiety, 32% were diagnosed with depression, and over 12% admitted to thoughts of suicide within the past 30 days from evaluation (Benningfield et al., 2010). Anxiety and other psychological disorders such as depression highly contribute to a propensity for relapse (Khazaee-Pool et al., 2019).

Postnatal women with OUD have a propensity for low self-esteem, ineffective coping, and may experience a sense of loss of control over their circumstances, which can lead to increased anxiety (SAMHSA, 2015b). Low self-efficacy usually accompanies OUD, which can lead to poor nutrition, health problems, altered sleep cycles, and severe depression (Currow et al., 2016). Women with OUD during pregnancy and the postnatal period usually internalize guilt and shame related to the negative social stigma associated with substance abuse, especially since they are also responsible for the consequences their drug use has on the fetus or newborn (DiReda & Gonsalvez, 2016).

Lack of Follow-Up Care

Up to 40% of women in the general population do not return for a postpartum follow-up appointment (ACOG, 2018). In 2017, 64.4% of women on Medicaid returned for a postpartum follow-up visit within 56 days from delivery; between 67.5% and 74.9% of women with commercial insurance returned for a visit (National Committee for Quality Assurance [NCQA], n.d.). The lack of early postnatal follow-up can result in several physical and psychosocial

problems for the women with OUD, missed opportunity for resources, and lead to relapse (Beckwith & Burke, 2015; Kocherlakota, 2014; Maguire et al., 2016).

The postpartum follow-up appointment customarily includes discussion regarding family planning and contraception, which can decrease the chance of unplanned pregnancy, a high-risk for this population (Thiel de Bocanegra et al., 2013). Although women are advised to abstain from sexual intercourse during the immediate postpartum period, many women with OUD go home to an environment that makes it difficult to withstand. It is common for these women to engage in sexual intercourse prematurely, leading to a subsequent early pregnancy (SAMHSA, 2015b).

Barriers to returning for follow-up in these women often include no childcare for the newborn or other children, fear of the possible loss of custody of children, fear of the reaction of the significant other (especially relevant if domestic violence exists within the relationship), inability to cope with anxiety and stress, lack of transportation, and lack of finances (SAMHSA, 2015b). Many women with substance disorders have developed negative connections with the medical and social professions that has led to distrust in providers, making it difficult for them to adhere to follow-up or reach out to meet sudden needs (Beckwith & Burke, 2015; Levine & Woodward, 2018; Maguire et al., 2016).

Lack of Support for Sobriety

Significant partners are oftentimes not supportive of the sobriety efforts of postnatal women with OUD. Many partners, family members, and acquaintances of the women are continuing to participate in negative lifestyle behaviors such as engaging in substance use, tobacco and alcohol use, and involvement in risky sexual behaviors (Krans et al., 2015). These

women are frequently victims of sexual and physical violence inflicted by their partners as persuasive techniques or punishment for refusing to engage in substance use (Krans et al., 2015).

Khazaee-Pool et al. (2019) found that five common causes of relapse in women with OUD were physical withdrawal complications, psychological distress of abstaining, family dynamics, socioeconomic factors, and cultural disparities. Studies have found that up to 63% of women with OUD lived with a person who also had a substance abuse problem, increasing the chance of relapse in these women (Dolan et al., 2012; Khazaee-Pool et al., 2019). Partners and family members have been known to express disappointment and anger toward attempts of the women to seek OUD treatment causing fear of retribution and abandonment (Khazaee-Pool et al., 2019).

Search Limitations

Although the amount of research has increased in response to the rising opioid abuse epidemic in the United States, interventions to understand how to treat this population have not increased with the same momentum (Brecht & Herbeck, 2014; Janisse et al., 2014; Tzilos et al., 2013). Specific research on OUD in pregnancy and postpartum, the care of the mother-child dyad, the care of infants with NAS, and the development of programs and pregnant and postpartum women with OUD make up a vulnerable population needing an increased focus on planning care to meet the many challenges faced on a daily basis.

More research is needed across all aspects of this patient dyad, including methods to deter and decrease the propensity for relapse in postpartum women; address the many psychological issues and sociological disparities that face new mothers with OUD; educating mothers on the signs, symptoms, treatment, and care of infants with NAS; the unique parenting needs of women during the fourth trimester; collaboration of health and community services to

provide one-stop care; and education to prepare nurses care for the patient dyad influenced by OUD.

Chapter Summary

This chapter documented the findings of a literature review and was conducted to describe variables related to the delivery of care to the postpartum women with OUD who were treated with MAT during pregnancy. Findings indicated that the standard treatment of OUD during pregnancy is MAT with methadone or buprenorphine, medications that decrease the cravings and withdrawal symptoms associated with abstinence of opioid use. Infants of mothers with OUD are susceptible to developing NAS, which exposes the infant to physical complications requiring a higher level of care. Mothers with OUD must be responsible for the increased level of care once the infant is discharged from the hospital setting. Women have a unique set of physical and psychosocial risks for and response to OUD than do men; this set of risks should be considered when planning care for women with OUD. A lack of a supportive environment during the year after delivery results in an increased propensity for relapse for these women.

Addiction theory can provide an understanding of the process of OUD and guide the understanding of the development of a comprehensive program for postpartum women with OUD. Koobs' (2020) theory of opponent process explains the transition of fear of consequences of opioid use to an overriding desire to provide relief from stressful situations. This drive to find a release leads women to attempt to overcome the difficulties associated with the fourth trimester, creating a propensity for relapse.

The following chapter will describe the methodology of this DNP project, which is a nonexperimental program design project to improve the mental, physical, and social well-being

of women with OUD while decreasing the risk of relapse and improve the quality of the mother-child dyad. The project included a systematic thematic literature review from evidence-based practice literature and professional and government agency guidelines; use of the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system of appraisal and the GRADE Evidence to Decision (EtD) framework to synthesize the evidence and form recommendations for a comprehensive postnatal follow-up program for women with OUD who were treated with MAT during pregnancy. The compilation of evidence and recommendations was presented to a panel of interdisciplinary stakeholders at a community hospital in the Texas Gulf Coast region that has seen an increase in pregnant women with OUD who are being treated during pregnancy for their input and consensus.

Chapter 3: Methodology

Corresponding with the rising rate of opioid use across the nation, the number of pregnant women with OUD is increasing at alarming rates (Brogly et al., 2018; Haight et al., 2018). Current best practice for these women is to follow a treatment plan that incorporates MAT during pregnancy to maintain a steady dose of opioids in the maternal-fetal bloodstream and avoid dangerous withdrawal symptoms in the mother and fetus (ASAM, 2015; Park et al., 2012). At a community hospital in the Texas Gulf Coast region, a gap in practice has been found to which there is no formal structured follow-up for postnatal women who have been treated with MAT for OUD during pregnancy. This gap in practice leaves this population of women at high risk for relapse to opioid use during a period that is characterized by numerous physical, social, and psychological complexities (Baldacchino et al., 2014; Schiff et al., 2018).

This DNP clinical guideline development process used best evidence literature, professional standards, existing program models, and expert input from an interdisciplinary panel of stakeholders to create a set of guidelines for a formal, comprehensive postnatal follow-up program for women who have been treated with MAT for OUD during pregnancy. The goal of the clinical guideline development project was to develop a set of clinical guidelines recommended by an expert panel; these guidelines will lead to enhanced nursing care for the postpartum women and improve outcomes for the mother-child dyad.

This chapter presents a further explanation of the design of the DNP nonexperimental project to include an explanation of the objectives and steps to be taken, the appropriateness of the chosen methodology, the role of the interdisciplinary team to promote interprofessional collaboration, a description of the practice setting, feasibility of the timeline for the project,

projected budget for executing the project, and the institutional review board (IRB) process for the chosen facility and Abilene Christian University (ACU).

Purpose

In response to an increase in the number of pregnant women at a community hospital in the Texas Gulf Coast region that have been treated with MAT during pregnancy for OUD, a need has been identified to develop a set of clinical guidelines to improve follow up during the first year after birth, also referred to as the fourth trimester. In an effort to decrease the risk for relapse in these mothers and to improve the care of the mother-child dyad, this scholarly DNP nonexperimental project systematically reviewed best evidence-based literature, professional guidelines, and theoretical models to create a set of guideline recommendations for a comprehensive postnatal program for this population to be presented to an expert panel of stakeholders for review.

Project Design

This DNP project used a clinical practice guideline design using the Delphi methodology through a multistage approach based on the application of the findings from a systematic thematic review of evidence, grading of evidence, and input from an interdisciplinary expert panel of stakeholders associated with the local community of the practice setting. The Delphi method focuses on guideline development through expert panel input with the goal of group consensus. Evidence-based recommendations and expert input were used to develop a formal, comprehensive set of guidelines and presented to the interdisciplinary panel for acceptance.

Four main objectives were set out. The first and fifth objectives each included two steps. The program design project was to be completed as follows:

I. Objective one: To prepare a thorough review and critique of evidence-based literature.
    a. Step one: Conduct a systematic thematic literature review from evidence-based practice literature and professional and government guidelines for the management of OUD during the postnatal period.
    b. Step two: Compile a critique of the reviewed literature using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system of appraisal.

II. Objective two: To synthesize the evidence using the GRADE Evidence to Decision (EtD) framework to form recommendations for a comprehensive postnatal follow-up program for women with OUD who were treated with MAT during pregnancy.

III. Objective three: To present a draft of the compilation of evidence and recommendations to a panel of interdisciplinary stakeholders at a community hospital in the Texas Gulf Coast region that has seen an increase in pregnant women with OUD who are being treated during pregnancy for input and consensus of expert opinion. This objective will be met using the Delphi method of gaining consensus of group opinion on recommendations for final guideline development. Qualitative data will be collected during this phase of the project.

IV. Objective four: To formalize and develop a final report of guidelines based on expert panel input and opinion that includes the structure, the evidence-based process guidelines, proposed formative and summative goals and milestones, and a proposed budget.

V. Objective five: To gain approval of the final compilation of evidence and recommendations after modification from a panel of the initial interdisciplinary stakeholders at a community hospital in the Texas Gulf Coast region.

   a. Step one: Present the finalized program guidelines of the comprehensive postnatal follow-up program for women with OUD who were treated with MAT during pregnancy to the initial panel of interdisciplinary stakeholders at a community hospital in the Texas Gulf Coast region that has seen an increase in pregnant women with OUD who are being treated during pregnancy.
   b. Step two: Use the International Appraisal of Guidelines Research and Evaluation (AGREE) II criteria as a checklist for the interprofessional review of the finalized formal, comprehensive guideline design.
   c. Step three: Qualitative data will be collected during this phase of the project and measured using a quantitative Likert scale.

Methodology Appropriateness

Literature Review With GRADE System of Appraisal

The first phase of the project commenced with a qualitative systematic thematic literature review from evidence-based practice literature and professional and government guidelines for the management of OUD during the postnatal period. The systematic research design allows the DNP student to gain insight into the information found during the systematic review as it applies to the particular circumstances and socioeconomic culture of postnatal women OUD (Polit & Beck, 2017). A systematic review of literature is a synthesis of evidence-based sources, with the purpose being to form an unbiased, comprehensive appraisal of all relevant evidence pertinent to a research question (Aromataris & Pearson, 2014). Systematic reviews stem from evidence found

in peer-reviewed current and historic literature and are often used to determine specific questions related to health care decisions and the design of guidelines (Aromataris & Pearson, 2014).

Systematic reviews seek to answer a defined research question while reducing the risk of bias during the process. Using the developed patient and population, intervention, comparison, outcome, and timeframe (PICOT) question for the program design project, a thorough search of available studies and guidelines started with the postnatal care of women with OUD who were treated with MAT during pregnancy. The Abilene Christian University library collection of databases, Campbell Database of Systematic Reviews, Cochrane Collaboration, and relevant professional and government agency websites were searched for qualitative and quantitative literature that met the designated inclusion and exclusion criteria.

Inclusion criteria included the care of pregnant women with opioid use disorder, postnatal care of women with opioid use disorder medication avoidance therapy for opioid use disorder during pregnancy, recovery models for women with opioid use disorder, neonatal abstinence syndrome, care of the infant with neonatal abstinence syndrome, and interdisciplinary care of pregnant women with opioid use disorder. Additional terms were included to field for outliers: peripartum, postpartum, pregnancy, opioid abuse, opioid addiction, substance abuse, and substance use. Exclusion criteria included women who are not perinatal or postnatal, incarcerated women, and women with addictions to multiple substances.

The GRADE method of appraisal was designed by the GRADE working group to critique bodies of evidence to help determine the strength of the recommended interventions for clinical practice. The GRADE system is currently used by over 100 reputable research organizations across the world, including the Cochrane Collaboration, the World Health Organization (WHO), and the National Institute for Health and Care Excellence (NICE; Alonso-Coello et al., 2016).

The GRADE method has three significant factors that make it different from other methods of literature review appraisal. These factors include (a) the quality of evidence is separated from the strength of recommendations, (b) the quality of evidence for each designated outcome is assessed separately, and (c) certain criteria determines the possibility for observational studies to be upgraded in reference to the quality of evidence (Goldet & Howick, 2013). The development of GRADE included consideration of the versatility of the method used across the scope of health care settings; therefore, the method can aptly be applied to community health care clinical practice questions (Dijkers, 2013).

The GRADE system is a five-step process where evidence is initially rated as *high* for randomized controlled studies or *low* for observational studies in step one. In step two, the initial ranking is either *upgraded* or *downgraded* (Goldet & Howick, 2013). Evidence can be upgraded for large consistent effect, dose response is proportionate to exposure, or actual effect is larger than suggested when confounders are removed and downgraded for risk of bias, inconsistency, indirectness, imprecision, or publication bias (Goldet & Howick, 2013). Step three assigns a final grade to the evidence of *high*, *moderate*, *low*, or *very low*, designating varying degrees of confidence in the end effect of evidence-based interventions in relation to the estimated effect of the intervention (Goldet & Howick, 2013). Step four considers other factors that may affect the appropriateness of recommending the intervention. These factors include the balance of desirable and undesirable effects, cost-effectiveness of the intervention, and the preferences of the targeted patient population (Goldet & Howick, 2013). The fifth and final step is to recommend using the intervention in terms of direction and strength: direction of recommendation as *for/against* and strength as *strong/weak* (Dijkers, 2013).

GRADE EtD Framework

Building on the GRADE method of appraising the strength of evidence, the GRADE working group developed the GRADE EtD framework to facilitate the process of transferring evidence practice. Alonso-Coello et al. (2016) stated the rationale of the GRADE EtD framework is to guide panels to "use evidence in a structured and transparent way to informs decisions in the context of clinical recommendations, coverage decisions, and health system or public health recommendations and decisions" (p. 361). The EtD framework allows for the adaptation of decisions and recommendations to fit the dynamics of the population to be affected, explains the pros and cons of the evidence, summarizes the evidence incorporating relevant criteria for decision-making, allows panels to follow a "structured and transparent" format for discussion, allows users of the final recommendations to identify supporting evidence for justification of panel decisions, and assists users to determine if recommendations should be adopted in their particular practice setting (Alonso-Coello et al., 2016, p. 361). The framework is comprised of three steps: (a) formulating a PICOT question, (b) making an assessment of the evidence, and (c) forming conclusions from assessments and judgments of evidence (Alonso-Coello et al., 2016).

Development of the Final Report of Guidelines

The role of the DNP nurse often calls for the translation of evidence into the development of guidelines that serve as practice-change protocols to increase the quality of care and improve outcomes "by reducing healthcare variations, improving diagnostic accuracy, promoting effective therapy, and discouraging ineffective – or potentially harmful – interventions" (Rosenfeld et al., 2013, p. S3). Used to translate best evidence into practice protocols, guidelines build a framework for which to "make better decisions, initiate quality improvement efforts, and

prioritize new research initiatives, and support coverage or reimbursement for appropriate services (Rosenfeld et al., 2013, p. S4). Clinical guidelines must be founded on strong best evidence, on certainty, not clinical judgment or previous nursing experience (White et al., 2016). Best evidence has been rigorously scrutinized by interdisciplinary teams and has been found to "direct a particular action" and can be "disseminated for use by many other professionals in the form of practice guidelines" (White et al., 2016, p. 168).

Local practice settings may develop clinical guidelines specific to the needs of the organization, community, and targeted patient population and adapt national or state guidelines to ensure applicability and feasibility within the practice setting (White et al., 2016). National and state guidelines may not efficiently address all aspects of a practice problem that is rapidly increasing in severity, such as the lack of follow up for postnatal women with OUD; interprofessional teams must work together "across all phases of the work of practice guideline development, implementation, and evaluation (Prior et al. as cited in White et al., 2016, p. 168).

As new best evidence is added to professional resources and databases, it must be integrated into practice in an efficient and timely manner, taking into consideration the evidence may be several months, or years, old by the time it is published (National Academies of Sciences, Engineering, and Medicine [NASEM], 2018). The methodology of this nonexperimental program design project includes an interdisciplinary team to critique, make recommendations, and apply the PWOUD Guideline criteria as a checklist to determine the credibility of the guideline design process. The guidelines will be based on the findings from the systematic literature review, GRADE system of appraisal, GRADE EtD framework, and input from the interdisciplinary expert panel. Theoretical models and literature from current recovery

programs for mothers with OUD will be reviewed and considered for examples when formatting guidelines and supplemental materials.

AGREE II Checklist

The AGREE II checklist tool is an internationally used method of monitoring quality and transparency during the development of clinical practice guidelines; the tool is also used to evaluate guidelines for credibility (Brouwers et al., 2016). The original version of the tool consisted of 23 items with definitions and detailed criteria related to quality and transparency of recommendations within guidelines; the tool was internationally tested for validity (Brouwers et al., 2016). The AGREE II tool was later developed from recommendations from several users and developers who had previously used the tool. The AGREE II tool has been adapted to create the new Postnatal women with opioid use disorder (PWOUD) tool used as a checklist the DNP can utilize to guide the development and assess the quality of clinical practice guidelines. The PWOUD checklist was used during the Delphi rounds presented to the interdisciplinary team of expert stakeholders.

Feasibility and Appropriateness

Feasibility for the proposed DNP project has been determined based on concern from the administration and the director of the labor and delivery unit at the clinical practice setting. There has been a voiced concern about the rising rate of pregnant women with OUD who have been treated with MAT during pregnancy presenting for delivery in the labor and delivery unit. A desire has been expressed in developing a plan to follow-up with these women after delivery to improve sustained care for the mother-child dyad and decrease the burden this problem has placed on the community. The facility leadership approved support for this project.

IRB Approval and Process

The IRB approval process was concluded with ACU before the initial phase project ensued (see Appendix A). According to instructions in the university's DNP resource course, the IRB application followed the approved proposal defense, chair, and committee approval. Prerequisites for IRB from ACU include proof of completion of an ethics module and education on human rights while conducting research. The required training for ethics was completed with proof submitted to ACU on February 2, 2020. The required training on human rights while conducting research was completed with proof submitted on February 3, 2020.

The required affiliation agreement between the project setting and Abilene Christian University has previously been finalized. Approval for the DNP student to consider the county's local facility for the proposed project has been granted by the administration and education department at the local practice setting (see Appendix B). The clinical practice setting may also require specific organization IRB approval. An application will be submitted to the facility upon ACU approval of the project proposal. There are no known conflicts of interest identified in the processes of the DNP practice project or between the proposed interdisciplinary team, the DNP student, and the clinical facility.

Interprofessional Collaboration

An interdisciplinary expert panel of stakeholders associated within the local community of the hospital practice setting in the Texas Gulf Coast region was to be enlisted to provide recommendations to the presentation of evidence determined through the GRADE appraisal and compilation of the EtD findings for the development of guidelines of a formal, comprehensive postnatal follow-up program for women who have been treated with MAT for OUD during

pregnancy. The panel of interdisciplinary experts was later presented with the final draft of the guidelines for evaluation using the PWOUD checklist.

The stakeholder panel was designed to include an obstetrician, a pediatric nurse, a social worker, an addiction specialist, a community health clinic advanced practice nurse who specializes in women's health, the director of the labor and delivery unit and nursing staff at a local hospital, a counselor from the local Woman's Center for Domestic Violence, and a grant writer.

Practice Setting for Evidence-Based Practice

The clinical setting for this DNP project is the community served by an acute care nonprofit hospital in the southern part of a county in the Texas Gulf Coast region. The hospital was originally established as a community hospital in 1969 and entered into a partnership in 2014 with a large academic hospital in a neighboring county. This merger with the large academic hospital opened access to a wide range of high-quality, innovative technologies, a diverse health care team, and outpatient services for the residents within the community. The hospital system has a clinic dedicated to pregnancy and maternal health located within the community. The Regional Maternal Child Health Program affiliated with this hospital system provides health care and a wide variety of maternal services to women within the area, offering reduced fees based on need. Permission has been granted to implement the project in the practice setting.

Although the county shares a border with a larger county where a major metropolitan city is located, the southern portion of the county where the project setting is located is approximately 51 miles from the metropolitan city's medical epicenter. The county's population is one of the fastest growing in Texas, with a population of over 330,000 residents. The county's poverty rate

is 9.89%, with the largest demographic being females age 25–34; females 35–44 are the second largest demographic living within the poverty level.

Target Population

Although this project's results will ultimately benefit women who have been treated with MAT for opioid use disorder OUD during pregnancy during the fourth trimester, the target population for this DNP project was the expert stakeholder panel who reviewed, critiqued, and approved the proposed guidelines. The panel was to consist of an obstetrician, a pediatric nurse, a social worker, an addiction specialist, a community health clinic advanced practice nurse who specializes in women's health, the director of the labor and delivery unit and nursing staff at a local hospital, a counselor from the local Woman's Center for Domestic Violence, and a grant writer. Not all panel members invited to participate were able to participate; additional interprofessional stakeholders were identified during the project's development.

Risks

There are no discernible health risks to the interprofessional team associated with the project. Informed consent to participate was acquired from the participating panel members (see Appendix C). Consent addressed all pertinent information to comply with ethical standards, including, but not limited to, explanation of the project, expectations of the target population, and right to withhold consent or terminate participation at any time during the project. Risks of compromise to the project's outcomes include the inability to assemble a diverse expert panel of stakeholders and the lack of participation from the identified expert panel during both face-to-face meetings to review recommendations and final guidelines. There are no financial risks identified. The project implementation cost was estimated to be low if using an online format to

deliver the research survey. The financial cost of project implementation was the responsibility of the DNP student.

Benefits

The project's short-term benefits include enhanced interdisciplinary collaboration between the members of the expert panel of stakeholders and vested interest for the designated facility in the care of a quickly growing patient population that requires a unique set of care interventions. The long-term benefits of acceptance of the project are numerous. Once the project is completed and guidelines are accepted, a pilot study can be conducted implementing guidelines and determining the adoption of a formal program into practice. Comprehensive care of the mother-child dyad will be enhanced, and quality indicators for this population will improve once the set of guidelines is introduced into practice. The financial costs associated with postpartum women with OUD, infants with NAS, and the negative effects of OUD on the family unit can be substantially reduced by implementing a comprehensive multidisciplinary program to address the needs of the affected population.

Instrument and Measurement Tools

The tools for recording the results of the systematic literature review include the GRADE system of appraisal table and the GRADE EtD framework table published by the GRADE working group. Permission to use the GRADE tools for educational and research purposes is not required by the GRADE working group. The original AGREE II instrument "may be reproduced and used for educational purposes, quality assurance programmes and critical appraisal of guidelines" or adapted for individual purposes as long as it is properly cited and the new title of the tool does not contain the AGREE name (AGREE Next Steps Consortium, 2017, p. ii; AGREE Enterprise, n.d.; see Appendix D & Appendix E). All three aforementioned tools are

available for free download on their associated organizational websites; training on use for all tools is also provided on the organizational websites. It is recommended by the authors of the original AGREE II tool that at least two experts appraise guidelines; an increase in the number of appraisers will increase the reliability of the results (AGREE Next Steps Consortium, 2017).

The new PWOUD checklist follows the format of the original AGREE II tool, which is comprised of a seven-point Likert scale ranging from 1 having the value of *strongly disagree* to a 7 having the value of *strongly agree* to rate 23 key points divided into six domains; two additional overall guideline ratings are addressed following the domain assessments (AGREE Next Steps Consortium, 2017). Like the original AGREE II tool, the new PWOUD Likert scale is a statistical tool that will allow qualitative data to be measured on a quantitative scale by assigning numerical values to expert stakeholder opinions expressed during the review of the proposed program guidelines. Two versions of the PWOUD instrument were used: first, during the formative Delphi rounds, a version omitting the two overall guideline ratings of the original AGREE II tool was used; and secondly, during the final review and acceptance of the comprehensive program phase, the PWOUD instrument included the overall guideline ratings to designate acceptance of the guidelines.

The domain scores are determined individually by determining the sum of individual key points within each of the six domains and calculating the percentage of agreement for each domain in order to score the tool (AGREE Next Steps Consortium, 2017). The percentage for each domain score is determined by subtracting the minimum possible score from the obtained score, then dividing this amount by the maximum possible score minus the minimum possible score and multiplying the quotient by 100. The following criteria can be followed to interpret domain scores. “Considering all domain scores: Users can create a threshold across all six

domain scores based on consensus or decisions by leadership [e.g., high-quality guidelines are those with domain scores that are all >70%"]; AGREE Next Steps Consortium, 2017, p. 10). The original AGREE II tool is accompanied by an instruction manual, which provides a descriptor for each domain, instructions on where to search for information needed for each item in a domain, and advice on how to rate each item (AGREE Next Steps Consortium, 2017).

Data Collection and Management and Analysis Plan

All data collected during the process of project implementation and analysis is stored as de-identified data. The data was stored in a secure Google drive provided by ACU under the DNP student's name. Data will become the property of the university in case access is needed at a future date. This drive storage system will be provided by the online graduate school for doctoral student research data and supported by the university's information technology (IT) department for security purposes. It will be kept for the minimum required time according to IRB guidelines.

This DNP scholarly practice program does not require statistical analysis. Qualitative analysis of literature review and grading of evidence will be recorded on the appropriate tools provided from the GRADE working group website. Scores from the PWOUDtool will be analyzed using the formula provided in the original AGREE II tool instruction manual.

Timeline

The timeline for this DNP project is represented in the table in Appendix F. Initiation of the project began at the time of enrollment in the scholarly program at ACU in June of 2018 and will commence at the time of the projected completion of the program in October of 2020. The practice project clinical site was secured in August of 2018. Draft composition of Chapters 1, 2, and 3 began in September of 2018. The first public defense of the proposal was completed in late

March of 2020. Once the proposal defense was accepted, approval from the IRB was initiated with the approval in early May of 2020. Upon approval, the DNP project's implementation phase began with a systematic literature review and grading of evidence. The results were completed and presented to the expert interdisciplinary panel of stakeholders in June of 2020 for the first Delphi study round of input. From these findings, formal guidelines were developed during the period from June to August of 2020. The second round of Delphi study methodology to present the formal guidelines to the panel commenced in August of 2020. Writing the fourth and fifth chapters of the DNP project occurred during a simultaneous period from June through August, culminating in September of 2020 during the DNP II course. The final defense was scheduled for October of 2020.

Chapter Summary

In response to a known gap in the transition of care during the postnatal period for women with OUD who were treated with MAT during pregnancy, the need for a formal, comprehensive program to follow-up with the mother-child dyad was determined. The purpose of this DNP practice nonexperimental project was to compile best practice evidence from scholarly sources and professional and government organizations into an EtD framework, which was appraised by an expert panel using the PWOUD tool to create a set of guidelines for the comprehensive care of postnatal women who were treated with MAT for OUD during pregnancy. This set of guidelines can ultimately serve as a grant proposal for a pilot study to contribute to knowledge regarding the care of this population and ultimately improve outcomes for the mother-child dyad.

Numerous interventions will be required to provide comprehensive care for postnatal women with OUD. The GRADE method of appraisal to analyze literature, the GRADE EtD

framework to recommend interventions, and the acceptance of a set of guidelines using a Likert scale with minimum-maximum ratings to support credibility will comprise a process that can be used to evaluate multiple interventions in one concise review. These methods are an appropriate system to critically assess existing best evidence with the goal of developing a set of effective clinical guidelines for this practice problem to address the needs of postpartum women with OUD and their infants.

Chapter 4: Results

Corresponding with the rising rate of opioid use across the nation, the number of pregnant women with OUD is increasing at alarming rates (Brogly et al., 2018; Haight et al., 2018). Current best practice for these women is to follow a treatment plan that incorporates MAT during pregnancy to maintain a steady dose of opioids in the maternal-fetal bloodstream and avoid dangerous withdrawal symptoms in the mother and fetus (ASAM, 2015; Park et al., 2012). At a community hospital in the Texas Gulf Coast region, a gap in practice has been found to which there is no formal structured follow up for postnatal women who have been treated with MAT for OUD during pregnancy. This gap in practice leaves this population of women at high risk for relapse to opioid use during a period that is characterized by numerous physical, social, and psychological complexities (Baldacchino et al., 2014; Schiff et al., 2018).

This DNP clinical guideline development process used best evidence-based literature, professional standards, existing program models, and expert input from an interdisciplinary panel of stakeholders to create a set of guidelines for a formal, comprehensive postnatal follow-up program for women who have been treated with MAT for OUD during pregnancy. This clinical guideline development project's goal was to develop a set of clinical guidelines recommended by an expert panel. These guidelines will lead to enhanced nursing care for the postpartum women and improve outcomes for the mother-child dyad. Further explanation of the design of the DNP nonexperimental evaluative project is explained in this chapter and includes the objectives and steps taken, appropriateness of the chosen methodology, role of the interdisciplinary team to promote interprofessional collaboration, description of the practice setting, feasibility of the timeline for the project, projected budget for executing the project, and the institutional review board (IRB) process for the chosen facility and Abilene Christian University (ACU).

Purpose of the Project

This scholarly DNP project's purpose was to utilize best evidence-based literature, professional guidelines, and theoretical models to design a guideline to serve as a basis for a comprehensive postnatal program for postpartum women with OUD to reduce the propensity for relapse and improve the mother-child dyad. The guideline would be used to determine if the opinions and input of an expert panel consisting of an interprofessional team would facilitate the development of the clinical practice guidelines for the target population. This project addressed the problem of the lack of follow-up for OUD in the postpartum period, also termed the fourth trimester.

Discussion of Demographics

A convenience sample was deemed appropriate for this study because the invited experts were already known to be qualified, had already expressed interest in participation, and had willingly provided email addresses as a means of contact. An invitation email was sent to prospective participants (see Appendix G). Inclusion criteria was that the participant is considered an expert in a profession relevant to the study, and they did agree to participate by completing the demographic portion of the study.

The project's target population was a panel of experts from multiple disciplines that hold an interest in the care of the postpartum women with OUD who were treated with MAT during pregnancy. All panel participants were practicing providers from disciplines within health care, mental health, and community services domains. Of the seven participants that completed all the study components, two are in the field of addiction services, two specialize in women's health, one specializes in mental health, one in pediatrics, and one is in social work. The panel consisted of three doctoral and four master's prepared members. Several of the panel members hold

degrees in more than one discipline. One holds a master's degree in psychology with a doctorate in addiction psychology, and six hold degrees in nursing. Of the three nurses, one also holds a degree in addiction services, one in mental health, and one in social work. The cumulative number of years of experience of the panel members was 118. All panel members were residents of the target community.

Data Analysis

Data analysis of this DNP project included data derived from each of the multiple steps involved in the project methodology. Data was collected from the rapid literature review, GRADE summary of evidence table, GRADE EtD framework, an interdisciplinary expert panel of stakeholders, and the PWOUDLikert scale. The PWOUDLikert scale checklist was used throughout the Delphi rounds scored using the method established by the authors of the tool and provided a means to measure data. An online survey generator was used to record responses. SurveyMonkey is a secure format that provides for anonymous responses and simple data analysis and presentation (Abd Halim et al., 2018). Permission from SurveyMonkey to use the format for academic research was granted (see Appendix H). Five main objectives were to be met using the design of the project. The first and fifth objectives each included two steps. The program design project was completed with the listed objectives in mind, including the following steps.

Objective One

Literature Review With GRADE System of Appraisal. The project's first objective commenced with a systematic thematic literature review from evidence-based practice literature and guidelines from both professional and governmental agencies for the management of OUD during the postnatal period. Due to the vast amount of research rapidly emerging to combat this

practice problem, I found it difficult to meet the components of an inclusive systematic review in the allotted DNP program's timeframe. Although systematic reviews are helpful to conduct research to support evidence-based practice, they should be exhaustive and can result in incomplete analysis when the researcher(s) are unable to devote the necessary time and resources to complete the reviews (Hartling et al., 2017). To decrease the risk of producing an incomplete review of the evidence, I determined it would be more beneficial in meeting the purpose of this DNP project within the allotted timeframe to focus research on three main interventions reoccurring throughout the literature search (see Appendix I).

Rapid reviews are endorsed by the World Health Organization (WHO) and are well suited for time-sensitive tasks such as guideline development and decision-making regarding recommendations as they provide concise and focused information on relevant topics (Hartling et al., 2017; Hartling et al., 2015; Langlois et al., 2018; Tricco et al., 2017). Rapid reviews are intended to address specific end-users rather than contribute to general knowledge. Hartling et al. stated, "rapid products are often conducted to help a specific end-user make a specific decision in an identified timeframe; therefore, the reviewers need to make decisions about what they can provide in the time allowed" (2017, p. 19). Existing professional guidelines to care for postpartum women with OUD were considered as examples of working models using evidence-based interventions. Grey literature such as policies, procedure manuals, guidelines, conference recordings, dissertations, theses, and factsheets was examined to add validity to the recommendations of best evidence to increase prolonged sobriety for the mother and improve family dynamics. The GRADE system of evidence of appraisal was used to evaluate the quality of the evidence. An evidence table was prepared to use when developing the guideline draft (see Appendix J).

Objective Two

GRADE EtD Framework. To build on the GRADE method of appraising the strength of evidence, the GRADE working group EtD framework was used to guide the expert panel's decision process. The GRADE approach to literature synthesis, appraisal, and transformation to a decision framework was found to be a much more extensive process than it first appeared. In a qualitative study of user experience with GRADE, it was discovered that the program presented multiple challenges with applicability for public health care policy and guideline development. According to Rehfuess and Akl (2013), these challenges were based on the complexity and multiple variables involved with the care of specific populations, including "(i) complexity of public health interventions, and (ii) choice of outcomes and outcome measures" (p. 9). Rehfuess and Akl (2013) also suggested the GRADE process is "not all-inclusive enough to apply to disciplines encompassing psychosocial domains due to the (iii) ability to discriminate between different types of observational studies, and (iv) use of non-epidemiological evidence" (p. 9). The GRADE guideline process and EtD framework are difficult for users without time-consuming training on the product due to complexity and terminology (Rehfuess & Akl, 2013). Many users of the GRADE process have expressed the desire for more simplified guidance and expanded options to rating the quality of evidence of psychosocial health interventions (Rehfuess & Akl, 2013).

Objective Three

Development of the Final Report of Guidelines. The third objective in the methodology was achieved by presenting a draft of evidence and recommendations to the expert panel of stakeholders. Theoretical models and guidelines from current recovery programs for mothers with OUD were reviewed and considered as examples when formatting the

recommendations. The Delphi method was used to gain consensus of group opinion on recommendations for guideline development. This method was appropriate to gain input from the panel members on the guideline recommendations. The PWOUDAGREE II checklist was used to collect both qualitative and quantitative data during this phase of the project to determine if further revisions were needed.

The top three interventions (use of an interprofessional, multidisciplinary team; home visits; and standardized checklists) discovered during the review of current guidelines and subsequent literature review were used as the basis for the draft of the guideline recommendations. The objective of the guideline was to serve as a foundation to construct comprehensive guidelines for a 12-month follow-up program for the care of postpartum women with opioid use disorder (OUD) who were treated with medication assisted treatment (MAT) during pregnancy. The guideline proposed that the use of a multidisciplinary team, home visits, and checklists as interventions would meet the purpose of providing a foundation for future program development. The guideline included pertinent information on stakeholder involvement.

Objective Four

Final Report. Objective four was to formalize and develop a final report based on the results of Delphi rounds to include the structured, evidence-based process guidelines, proposed formative and summative goals and milestones, and a proposed budget (see Appendix K). Because the overall outcome of the project served only to prepare a limited foundation intended to be used for future guideline development, proposed formative and summative goals and milestones and proposed budget were not included in the final report. The draft of the

recommendation guidelines was edited to include input from the expert panel resulting in a finalized report.

Objective Five

Guideline Recommendations. The final guideline recommendations were to design a formal, comprehensive program for postpartum women with OUD who were treated with MAT during pregnancy using the following three interventions as a foundation for development: the use of a multidisciplinary team, home visits by a health care provider, and the use of standardized checklists to form a foundation for care of the mother-child dyad. Evidence was provided to support these interventions. Psychosocial, socioeconomic, and physical health issues can be improved through collaboration between multiple disciplines. Home visits or "check-ins" using texting or phone calls can give the health care provider a look at the home environment and interrelationship dynamics in the home. Adding this dynamic to care for this population can give the provider a better sense of the needs of the client. Checklists can be used to accurately document assessments and ensure all aspects of care are addressed. They can also be used as tools to measure improvement or discover areas for further examination.

Results of the PWOUDChecklist

Two Delphi rounds using the PWOUDchecklist adapted for SurveyMonkey were completed. After the first round, scoring and comments from the completed PWOUD checklist served as a basis for revisions of the guideline. Three participants provided comments during the first round of the Delphi study. Two were agreement statements. One participant stated, "Excellent, the topic is pertinent to today's society." Another participant stated,

> Opioid addiction is a problem across society. This practice guideline will be useful in an effort to provide supports for mothers and their newborns and will facilitate contact that

> may help bridge the gap between postdelivery and home discharge and clinic provider visits. Newborns will have gains not previously experienced through increased efforts in maternal bonding and care.

One panel member provided a comment addressing the need for clarification of items within the guideline corresponding to PWOUDitems. The guideline was revised based on the following input provided by this panel member.

> The author compiled a strong collection of supporting evidence to guide [the] development of what would likely be a solid perinatal monitoring program for both the mother and child. While the objectives of the guideline are initially somewhat nonspecific, particularly regarding outcomes assessment for the child, the bulk of the proposal becomes, for the most part, self-explanatory and the consideration that was taken in both completing the background research and developing the resultant recommendations is apparent. My main concern with the document is MAT does not refer to "medication avoidance therapy." This acronym is known in the addiction field to designate "medication assisted treatment." Please perform a web search on medication avoidance therapy. You will find the term is not significantly used; however, medication assisted therapy is widely known.

Additionally, items that were scored lower than *strongly agree* on the PWOUDchecklist were revised.

Revisions included additions to the guideline presentation. Further discussion of panel members being identified as anonymous experts in multiple disciplines included mental health, addiction services, registered nurse leadership, social work, women's health, pediatrics, and community services. The end target population was identified as postpartum women with OUD

who were treated with MAT during pregnancy. It was noted that the future development of a formal program would include the views and preferences of the end target population. Criteria and methods for selecting evidence for the literature review and linking results to recommendations were included in the guideline. Upon suggestion from a panel member, it was decided to change the terminology in the guideline from “medication avoidance therapy” to “medication assisted treatment.” All aspects of the PWOUDchecklist were included in the guideline recommendation.

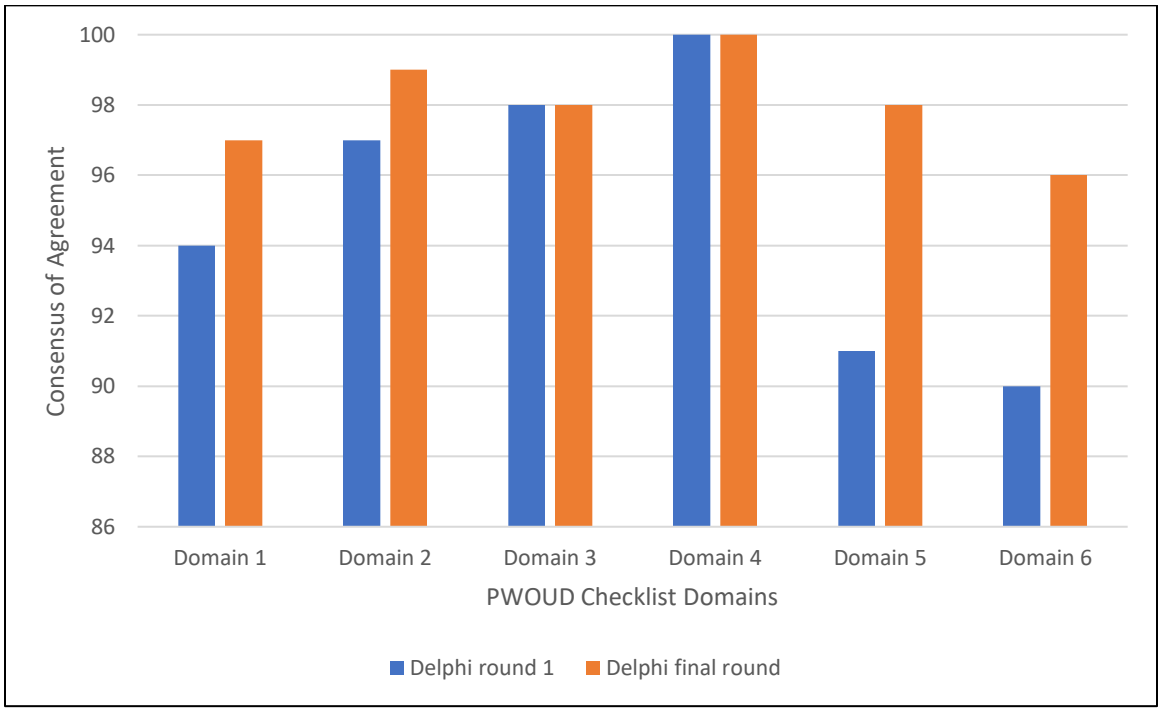
The checklist was scored during both rounds. The Agree Enterprise website provides an instruction manual to separately score each of the six domains on the PWOUDchecklist. There is not a total score for the entire checklist, rather a score for each domain. The scores of all individual items in a single domain are added together and calculated using a formula to determine an overall percentage rating for the domain.

The instructions for the tool do not designate a percentage at which consensus is said to be met, leaving this for the user to determine. For the purpose of this guideline project, consensus was determined on the final Delphi round by asking the panel to rate the overall quality of evidence and if they would recommend the guideline for use to develop a comprehensive program. In respect to the first Delphi round, the scores of each of the six domains increased or remained the same with the final presentation of the guideline. Both rounds resulted in a percentage consensus of 90% or greater on all six domains. The lowest score on the first round was 90% for domain six, editorial independence; the highest score was 100% for domain four, clarity of presentation; the median score of all domains on round one was 95.5%. For the final round, the lowest score was 96% for domain six, editorial independence; the highest score was 100% for domain four, clarity of presentation; and the median score was 98%. The

percentages of consensus for each round of the Delphi study are recorded in the following figure (see Figure 2).

Figure 2

Percentage of Consensus on PWOUD Guideline Delphi Rounds



Note. Consensus of agreement is measured in percentage.

Question Guiding the Inquiry

The PICOT question guiding the research was: Will an interprofessional team be able to develop clinical practice guidelines for a program to follow women treated for opioid use disorder during pregnancy with medication avoidance therapy after birth? The methodology used during the implementation of the project showed that an interprofessional team was able to develop clinical practice guidelines for a program to follow women treated for opioid use disorder during pregnancy with medication avoidance therapy after birth. The guidelines developed by the team were not all-inclusive for a formal, comprehensive program for the

subject population but can be used as a foundation to develop a more detailed program further. The findings of the PWOUDchecklist to evaluate the formal guidelines presented to the panel resulted in a consensus scoring of 90% or above on all six domains. The panel members were 100% in agreement that the presented guidelines were acceptable as a foundation to base a more comprehensive program.

Reliability and Validity

Reliability and validity of the findings were supported by the methodology and tools used to conduct this DNP project. Although the methodology resulted in a positive correlation to the research question guiding the project, the tools used during the process were met with challenges and adjustments were made. Systemic reviews on topics with vast amounts of new research can take large amounts of time and resources to conduct. Rapid reviews are not as time-consuming or exhaustive as systematic reviews, however, they are effective at synthesizing evidence for guideline development and health care decision-making (Hartling et al., 2017; Hartling et al., 2015; Langlois et al., 2018; Tricco et al., 2017).

Tools from the GRADE working group are endorsed by the WHO and have been tested extensively for reliability and validity by various research-based organizations throughout the world (Alonso-Coello et al., 2016). The GRADE tools are structured to be best applied to more extensive review and guideline development projects than were conducted in this DNP project. Because the review subject contained psychosocial and mental health dynamics, the GRADE method of determining levels of evidence was not appropriate for this study, as the method automatically downgrades for any research that is not a randomized study (Goldet & Howick, 2013). The GRADE approach to literature synthesis, appraisal, and transformation to a decision framework was found to be a much more extensive process than it first appeared. In a qualitative

study of user experience with GRADE, it was discovered that the program presented multiple challenges with applicability for public health care policy and guideline development (Rehfuess & Akl, 2013). The PWOUDchecklist, coupled with a Delphi methodology, produced a reliable means to gain consensus on guideline assessment.

Chapter Summary

This DNP project investigated whether an interprofessional team would be able to develop clinical practice guidelines for a program to follow women treated for opioid use disorder during pregnancy with medication avoidance therapy after birth. The project used a multistep methodology including a rapid review of literature, grading of the evidence, completing an evidence to decision framework, compiling a draft of recommendations that were presented to an expert panel through two Delphi rounds and the PWOUDchecklist, formulating a final guideline, and gaining consensus of agreement from the expert panel. The results of the project did show that an expert panel of expert stakeholders could generate consensus on a guideline to develop a comprehensive program for postpartum women with OUD who were treated with MAT during pregnancy. Chapter 5 further discusses the study's findings and interpretation as it applies to leadership and the essentials of doctoral education for nurses. Recommendations for future research will also be discussed.

Chapter 5: Discussion of Findings, Recommendations, and Conclusions

The purpose of this DNP project was to utilize best evidence-based literature, professional guidelines, and theoretical models for the design of a comprehensive postnatal program for postpartum women with OUD who were treated with MAT during pregnancy. The project used a multistepped methodology including a review of literature, grading of evidence, presentation of a guideline draft to an expert panel of stakeholders in the care of the end target population for input through Delphi rounds with the PWOUDchecklist. The expert panel provided feedback to base revisions of the guideline draft to a final document that was presented to the panel for consensus of acceptance. The panel consisted of seven interdisciplinary experts practicing in the fields of nursing, addiction services, women's health, mental health, pediatrics, and social work. Two rounds of the Delphi study with the PWOUDchecklist were completed resulting in group consensus to adopt the guideline. The interpretation and inference of the findings of this project are discussed in this chapter. An analysis for leaders will be presented, and the relationship between the findings and the eight DNP essentials will be examined. Recommendations for future clinical practice and research will be included.

Interpretations and Inference of the Findings

The research question guiding this project asked if an interprofessional team would be able to develop clinical practice guidelines for a program to follow women treated for OUD during pregnancy with MAT during the postpartum period. Several steps were taken to determine the outcomes of the research question. Every step of the methodology revealed findings that related to the outcome of the project. Certain steps resulted in more positive conclusions, specifically, the literature review, Delphi rounds, and use of the PWOUDtool to measure consensus. Findings from the primary and secondary literature reviews substantiated the

necessity for models of care for postpartum women with OUD who were treated with MAT during pregnancy. Three main interventions were determined to best serve as the foundation for further development of a larger program. These interventions are a multidisciplinary team to guide care, home visits to assess and provide care, and checklists to document care. Other steps resulted in inconclusive or inauspicious outcomes such as the GRADE table of evidence and EtD framework. The overall goal of the project was to create a formal, comprehensive follow-up program for postnatal women with OUD who were treated with MAT during pregnancy to address the physical, psychosocial, and environmental needs of the population to improve the mother-child dyad. This project's goal to develop a comprehensive set of guidelines to care for the target population through an expert interdisciplinary panel's input and consensus was partially achieved. The project's results showed that the use of an interprofessional panel of experts could be used to develop a guideline; however, it was determined that the development of a formal, comprehensive program for the target population was not feasible within the scope of this DNP project.

A GRADE table of evidence was completed to summarize the results of the rapid review of the literature. The findings of the table of evidence were inconclusive. Within the GRADE framework, research must be categorized as randomized trials or observational studies. Much of the population health, mental health, and substance abuse research included in the rapid literature review included observational or nonrandomized studies. The GRADE program downgrades the quality of evidence for any evidence not designated as a randomized study, automatically labeling the work as low-grade evidence (Goldet & Howick, 2013). Additionally, there are no provisions to incorporate expert opinion or grey literature; therefore, they are not considered in the GRADE summary of evidence or the EtD frameworks. Information gained from sources such

as professional guidelines, government agency policies, fact sheets, and expert clinician recommendations were excluded from the review and used only as unofficial resources to substantiate the evidence.

I used the EtD framework to track the project implementation progress, but the product was not disseminated to the expert panel members. Although being excellent for the tasks associated with formulating clinical pathways and health care policies, utilization of the entire program requires extensive time, training for both researcher and end-user, and requires substantial financial resources to upgrade to a professional product. The GRADE EtD program would be a valuable resource for more extensive projects. This program could contribute to the future development of a formal, comprehensive program to provide care to postpartum women with OUD.

The findings showed evidence that a multidisciplinary team could provide input from various perspectives on the care of the mother-child dyad, leading to a more comprehensive foundation on which to base a formal program for the target population. The multidisciplinary team reached a consensus on an initial guideline to design a more comprehensive program. Consensus was achieved in two Delphi rounds using the PWOUDchecklist. The combination of both methods proved to be beneficial to making population care decisions and could contribute to future initiatives by nursing leadership. It also indicated that nurse-led strategies incorporating collaborative interdisciplinary care could meet the needs of this population.

This project contributed to existing nursing knowledge regarding both the care of postpartum women with OUD and the use of an expert panel of interdisciplinary stakeholders to guide the development of a program to meet the complex needs of this population. The exponentially growing opioid epidemic has triggered vast research on the subject over the past

few years. Although much research has been conducted on care pathways for those affected by opioid use, the research on diverse care for special populations such as postpartum women with OUD has not been as extensive (ACOG, 2017; Hadland et al., 2020). This project revealed that much more research is needed to reduce the propensity for relapse for women with OUD and to improve outcomes of the mother-child dyad.

Limitations

This DNP project was met with several limitations. The first limitation manifested before the implementation of the project. As previously discussed, the setting of the project was to be a local community hospital where there had been an increase in the number of deliveries to women with OUD who were treated with MAT during pregnancy. The majority of these women obtained care from a local physician who was on staff at this hospital. The physician was providing obstetrical care while treating them with MAT for OUD. There was a need for a postpartum program for this population since many of these women were lost to follow up after discharge from the hospital. Originally the panel members were to include this physician, select members of his clinic staff, and employees of the labor and delivery unit and social services department of the hospital. During the proposal writing process of this project, the physician unexpectedly expired and the practice was closed. Other physicians affiliated with the hospital system shared obstetrical care of the women until delivery, but there were no physicians to continue MAT. The sudden loss of the physician not only became a limitation to the initial plan for the DNP project but also brought an even greater need for community-wide care of peripartum women in the community. The project was modified to include interprofessional experts from the entire community who now held a stake in this population's care.

The project's methodology presented an unanticipated limitation to the timeline concerning implementation. The literature review became more time intensive than planned. With opioid misuse and addiction being a pressing issue in the health care and political arenas, the amount of current literature is massive and growing rapidly. It was determined that an exhaustive systematic review on best evidence-based practice for the postpartum care of women with OUD should be the singular methodology of a DNP project instead of one of many steps to implementation. Instead of a systematic review, a rapid review was incorporated into the methodology, resulting in concise evidence to support evidence-based practice interventions to serve as a foundation for a more detailed program at a later date. The GRADE EtD framework also became a limitation due to its complexity and extensive training required to use. The program required interaction between all panel members during the multiple processes involved in completing the framework, with training required to manipulate the program (Alonso-Coello et al., 2016).

The most significant limitation resulted from the outbreak of the COVID-19 pandemic, which limited access to the panel of interdisciplinary experts. Because of social distancing imposed during the COVID-19 pandemic occurring at the time of this DNP project implementation, it was not feasible to implement the full GRADE EtD guideline development process due to limited face-to-face interactions with panel members. Additionally, many of the panel members were under strict time constraints due to excess patient care workload or were directly experiencing health complications from the disease itself. Thus they were unable to devote the time and effort needed to be trained on the use of the GRADE product. The training for the EtD program was considered to be too arduous for the panel during this time. The EtD framework was used to develop the rough draft of the guideline, but a streamlined guideline

development process was used with the panel members, which did not require additional training for the panel.

Implications of the Analysis for Leaders

This project has shown that nurse leaders have the ability and the responsibility to develop strategies to address the opioid epidemic. In particular, the profession of nursing is well-suited to provide care and develop pathways to care for affected populations with diverse psychosocial needs such as postpartum women with OUD. Since the inception of the profession, nursing has been considered to have a foundation built on caring and forging healing relationships to bring clients to a place of optimal physical, spiritual, and emotional health (Adams, 2016). Nurse leaders have the qualities and education to make judgments that result in effective recommendations to lead guideline development teams to care for the complexity of the target population. Nursing leaders, with knowledge of all dimensions of wellness, are in a prime position to lead multidisciplinary teams to develop programs aimed at healing the whole person—spiritually, emotionally, and physically.

Leadership is responsible for the continuing education of those they lead; as new research reveals the need for systemic cultural change, nurse leaders should initiate endeavors to ensure their constituents are educated on ways to achieve transformation to a judgment-free environment. Many postpartum women with OUD have expressed the behavior and demeanor of health care professionals has left them feeling shame, guilt, and inferiority (Cheng et al., 2016; SAMHSA, 2018; Schiff et al., 2018). Educational programs that can reduce the stigma nurses may be inadvertently portraying to these women should be a priority of nurses in leadership.

In the role of nursing leadership, the DNP nurse should be active in advocating for health care policy to eradicate the disparities and inequalities of underserved populations (Moran et al.,

2020). Women with OUD face many obstacles in gaining the care they need to maintain sobriety and flourish in daily life. They often feel powerless to change their financial, environmental, and psychosocial conditions. Pregnancy is generally covered by some form of insurance, but most public coverage ends after delivery, leaving women without private insurance without coverage for health care costs. Even with private insurance, coverage for substance abuse or mental health is often limited. Nurse leaders can lobby initiatives aimed at extending the time for Medicaid coverage during the postpartum period, which could decrease the incidence of postpartum OUD, anxiety, depression, suicide, and opioid overdose by improving continued access to health care services for postpartum women with OUD.

Suggestions for applying the findings of this research to clinical practice can be grounded in the DNP Essentials for the Doctoral Education for Advanced Nursing Education Practice, which provides a model for advanced practice nursing (American Association of Colleges of Nursing, 2017; Zaccagnini & White, 2017). During this nurse-led guideline development project to provide a foundation for the care of postpartum women with OUD who were treated with MAT during pregnancy, an interdisciplinary team of experts was able to come to an agreement on a plan to care for the mother-child dyad. Application of the findings of this project will be discussed as they relate to the eight DNP Essentials.

Evidence-Based Findings and the Relationship to the DNP Essentials

Essential I: Scientific Underpinnings

During this DNP project, the research provided evidence that treatment for postpartum women with OUD requires more than medically treating a disease. Care of the postnatal woman incorporates treating the whole person—spiritually, emotionally, and physically; it also includes treating the infant and intervening to improve the mother-child dyad. The combination of

evidence-based science of medicine with philosophical, ethical, and theoretical-based nursing provided a model to address all dimensions of a human being to meet the unique set of needs of postpartum women with OUD. Just as the interdisciplinary team of experts merged knowledge from various disciplines to reach a consensus on the guideline presented, the subject matter of this DNP project required a merging of scientific medical knowledge of addiction and MAT with philosophical knowledge of the client's beliefs, values, and emotions to provide holistic care. Results of this research reiterated that nurses are often the front-line providers for patient populations, especially in areas of community health. In a program to care for postpartum women with OUD, the DNP would be the eyes and voice of this population by serving as leaders on multidisciplinary teams developing care models for these women and their infants.

Providing care for this population is laden with instances where ethical and analytical judgment forms the basis of decision-making. This research has shown that several dimensions influence the propensity for relapse in these women; there is no unequivocal answer that serves the population as a whole. For instance, if a woman admits to relapse, does this mean her children should unquestionably be removed from her care? Does this mean she should be dismissed from the program? Does this mean she should be incarcerated in jail or inpatient rehabilitation? These are questions that the DNP must analyze and judge when providing face-to-face care for the postpartum women with OUD, whether the DNP is leading the multidisciplinary team or whether the DNP is providing input for the design of a program to care for the target population.

Scientific underpinnings of nursing are guided by science blended with theory (Zaccagnini & White, 2017). The theoretical framework guiding this DNP project was the opponent process theory (OPT), which explains how the person with OUD sees risky opioid

misuse as a reward rather than an action that can result in negative consequences; the fear of repercussions is replaced with feelings of relief (Koob, 2020). The nurse must understand the physiological changes of addiction on the body are coupled with emotional and behavioral manifestations that skew the client's ability to differentiate between negative and positive reinforcement. The postpartum women with OUD often live with the effects of past trauma and abuse, which has contributed to a history of substance abuse as an escape mechanism. It is natural for these women to develop cravings leading to relapse when they feel anxious or desperate (Koob, 2020). By applying scientific and theoretical knowledge, the DNP can plan integrative care for postpartum women with OUD.

Essential II: Organizational and Systems Leadership

This project took on the organizational systems viewpoint inherent in the DNP essentials, which examined the entire process of care for postpartum women with OUD who were treated with MAT during pregnancy. The project first looked at the opioid crisis as it affects the United States population as a whole, then the problem was broken down so project development could gain a full understanding of the many dimensions of OUD and the unique needs of the target population. By approaching the project, and ultimate solution, with an organizational viewpoint, it is known that all members of the care team, no matter what rank or duty, are responsible for making the system work effectively (Zaccagnini & White, 2017). From the leader of the guideline development team to the postpartum women with OUD, all must do their part to achieve successful outcomes.

During this research, it was decided by the interdisciplinary panel of experts that a formal, comprehensive program based on foundation guidelines incorporating a multidisciplinary team approach, home visits, and checklists to track care could meet the needs of postpartum

women with OUD who were treated with MAT during pregnancy. Future development of a larger program that addresses the many physical, psychosocial, environmental, and socioeconomic needs of this population will require organizational and systems leadership tailored for the role of the DNP. The panel of experts for this project included addiction specialists, a social worker, and nurses specializing in mental health, pediatrics, and women's health. There are many other roles for nurses and other mental and physical health care providers in a more comprehensive program. Under the direction of nursing leadership, the program could be staffed with nurses in multiple specialties and with varying certifications. The areas for certification and training for nurses is immense. As the program grows, nursing leadership can reach out to community partners creating alliances to provide additional services to further enhance the care of the target population.

A financial budget will eventually have to be determined to ensure the organization can operate successfully. Funding will require an expert in monetary acquisition such as a grant writer. It is recommended that the DNP should assume this responsibility or seek out a professional grant writer. Financial costs of building a comprehensive program were not discussed in this project; however, it is believed that funding from government and health care organizations could provide the money needed to operate such a program. It is estimated that costs for such a program could be extensive. A similar program in a central Texas city reports annual costs of up to $400,000 depending on resources available to the program (Cleveland et al., 2015). This particular program receives funding from grants from SAMHSA and local health care systems (Cleveland et al., 2015).

Essential III: Clinical Scholarship and Analytical Methods

This qualitative DNP project utilized several methods to synthesize evidence-based literature, analyze results, and transfer the evidence to implement a quality improvement program for the care of postpartum women with OUD who were treated with MAT during pregnancy. The project further implemented a guideline evaluation as a research method. According to Zaccagnini and White (2017), different types of qualitative studies can be used to enhance nursing practice, including "critical social theory, ethnographic studies, grounded theory research, historical research, phenomenological studies, and philosophical inquiry" (p. 75). This research fell into two of these categories: critical social theory since the research on a population (postpartum women with OUD) met with many inequalities and socioeconomic disparities, and ethnographic research was incorporated in two ways: by including views of the target population in literature reviews and by gaining commentary from the expert panel.

A review of the literature resulted in development of a guideline based on three evidence-based interventions to provide care to postpartum women with OUD who were treated with MAT during pregnancy. The literature review contributed to current research by integrating the three interventions into a care bundle to serve as a foundation for later development of a more comprehensive program. The evidence was synthesized using the GRADE method of literature analysis, which did not result in a strong representation of the evidence due to the operational constraints of the tool. Other tools to critique literature can be used by the DNP to rate the quality of evidence for health care with a heavy mental or social health basis. The PWOUDwas used in Delphi survey rounds to rate the guideline drafts until the expert panel of stakeholders determined a consensus. The use of the tool was determined to be a beneficial aspect of the

research methodology. The tool could be used for future evaluation of additional guidelines as the project continues to develop.

Essential IV: Information Systems and Patient Care Technology

Throughout the implementation of this DNP project, the use of information systems and Internet technology were used to review literature, communicate with expert panel members, collect and analyze data, and disseminate results. Information systems to care for the target population were recommended in the literature review. The accepted foundation guidelines included recommendations to interact with the target population using technology to enhance the delivery of care. Online searches of publicly available search engines and private databases were accessed during this project to examine evidence-based literature and general knowledge. Several online tools were used to critique evidence and develop quality improvement guidelines. The GRADE evidence table and EtD framework were online information systems used to facilitate research.

The AGREE II tool was downloaded from an online source available for free to developers of practice guidelines. An online format of the tool was said to be available but was not used because the link to the online survey was inaccessible throughout the implementation process. Instead, the tool was distributed to the expert panel using a secure online survey format called SurveyMonkey. The format allowed for the AGREE II to be adapted to the PWOUD checklist and presented as an online survey assessable through an emailed link. A link on the initial consent directed the expert panel participant to an instructional presentation and a demographic questionnaire and the PWOUDchecklist. SurveyMonkey also allowed for the development of analytical graphs and charts and a PowerPoint presentation of the results of the

survey. This presentation could be used in the future development of a more formal, comprehensive program for the care of the target population.

One of the essential purposes of meaningful use (MU) is to improve the quality and safety of patient care and improve outcomes for any patient population across the health care spectrum (McBride & Tietz, 2016). In addition, MU is meant to improve the coordination of care among numerous patient encounters, reduce errors and omissions of health care, and provide patients with access to their medical history and treatment plans (Agency for Healthcare Research and Quality, 2015). This research found that home visits and using standardized checklists can improve the coordination of care of the mother-child dyad. One recommendation to facilitate regular interactions between the health care provider and the client was to use cell phones for check-ins, reminders, communication, and education. Electronic checklists can be used to provide consistency in assessment, documentation, and guarantee a standardized criterion to which outcomes can be measured and evaluated.

Essential V: Health Care Policy

The aspect of health care policy as it applies to nursing leadership within this DNP project's scope using an interprofessional panel of experts to develop a set of program guidelines can be met by including local and state government officials in the guideline development process. During the research phase of this DNP project, a member of the Texas House of Representatives was contacted to inquire about state legislation to address maternal mortality and initiatives to address OUD during the peripartum period. According to the representative, numerous bills have been filed by House members that focus on improving maternal health and seek to provide resources to identify and treat women at risk for poor health outcomes during and after pregnancy (D. Bonnen, personal communication, March 22, 2019). Doctor of Nursing

Practice-prepared nurses have an obligation to lobby for legislation that addresses health disparities and the unique needs of special populations. Several bills can be supported that seek to establish statewide programs to improve maternal and newborn health for the target population.

According to the representative, legislative efforts to improve maternal health care in Texas remain committed to addressing maternal mortality and morbidity (D. Bonnen, personal communication, March 22, 2019). State and national funds have been set aside for the care of women, children, and families affected by the opioid epidemic. Advanced practice nurses have successfully lobbied to create programs for prenatal and postnatal care via telemedicine, inpatient treatment medical homes for pregnant women with mental and substance abuse disorders, and training courses that target women of childbearing age to help prevent OUD and negative outcomes (D. Bonnen, personal communication, March 22, 2019).

Essential VI: Interprofessional Collaboration

This DNP project was based on determining the extent which interprofessional collaboration could influence the construction of a guideline to care for postpartum women with OUD who were treated with MAT during pregnancy. All phases of the project incorporated interprofessional collaboration, from the literature review, which included studies and theoretical models from multiple disciplines, to the expert panel's final consensus of the recommendations. This interprofessional team was able to thrive under the direction of nursing leadership to successfully collaborate in defining a set of guidelines to provide care to a multidimensional patient population. Nursing leadership recognized barriers and limitations to communication within the panel and effectively developed strategies to overcome them. The limitations in communication resulting from the COVID-19 pandemic social distancing restrictions may have

reduced the amount of discussion between panel members. However, each member of the interprofessional team of experts was provided with an opportunity to input comments on the PWOUDchecklist based on their unique sets of professional knowledge. Through trusting partnerships centered on mutual respect, the DNP leader has the essential skills and knowledge to lead practice change interprofessional teams effectively.

Essential VII: Clinical Prevention and Population Health

The interdisciplinary team that participated in this DNP project agreed on the set of initial interventions as a guideline to develop a more intricate and extensive future comprehensive program with the goal of providing care for postpartum women with OUD who were treated with MAT during pregnancy. The outcome of a care pathway for this population is to prevent the mother from relapsing and help her maintain sobriety. This DNP project was a clinical prevention and meant to enhance not only the quality of life for this specific population but to increase the quality of health and outcomes for a much larger domain. By keeping the mother from relapsing and developing a program rich in interventions to support and improve health outcomes for the mother, child, family unit, community, and society. This project aimed to provide care to a target population that serves as the core of the family unit, the foundation of the next generation, and the status of society's future. By improving the mother-child dyad in the present, the future of the next generation is also improved.

The role of the DNP prepared nurse in the fight against substance abuse, in general, is immense. This is particularly true within the realm of postpartum women with OUD. One of the main responsibilities of advanced practice nurses is the promotion of physical and mental health through preventative education (Zaccagnini & White, 2017). Teaching topics pertinent to the target population include nutrition, breastfeeding, assessment for onset or complications of NAS,

NAS soothing techniques, infant massage, anger management, stress management, tobacco exposure, domestic violence prevention, parenting skills, home safety, family planning, and other individualized teaching needs. Other preventative measures that should be undertaken by the DNP are those pertaining to the referral of the postpartum woman with OUD to counseling and mental health service, social services, and community programs that can help improve psychosocial and socioeconomic obstacles.

Essential VIII: Advanced Nursing Practice

The role of the DNP is evolving every day, encompassing clinical, administration, and education practice. The problem addressed in this DNP project was the increase in the number of postpartum women with OUD who took MAT during pregnancy and who were subsequently lost to follow up in the postnatal period. These women were at risk for relapse and recidivism. The gap in practice was that there was no formal, comprehensive program for postpartum follow-up of these women. Findings from this project showed that there is a place for DNP practice in the clinical, administrative, and educational aspects of the provision of care for postpartum women with OUD who were treated with MAT during pregnancy. Clinical DNPs have the advanced clinical judgment and critical thinking skills to provide care at the personal level; DNPs in leadership have the skills to lead care initiatives and mange operations involved with the development and maintenance of programs to care for the target population, and DNPs with educational backgrounds have the knowledge to continue research on innovative care for the population and to educate the next generation of nurses on the evidence-based delivery of nonjudgmental and nonbiased care. Doctors of Nursing Practice practicing in all specialties have the responsibility to lobby for policy changes and value-based care for the mother-child dyad.

Recommendations for Future Research and Clinical Practice

Each discipline that is involved in the treatment of postpartum women with OUD who were treated with MAT during pregnancy confronts the complexity of this duty from a differing viewpoint. Traditionally, each of these disciplines provides their own care pathways and care structures, creating a fragmented system. The move to collaborative care for the target population may be difficult, but evidence shows the effort results in improved outcomes for this population. The recommendation for the future of integrated care for this population is to research methods to facilitate the merging of health care, mental health, social services, and community services into a cohesive program. Professional education to a multidisciplinary workforce is needed to teach methods to provide care in a nonjudgmental way that will reduce the stigma and shame many women with OUD experience.

This DNP project addressed a very small portion of the research needed to make an impact on the enormous problem of perinatal opioid misuse that is prevalent in all areas of the country. It was not possible within the scope of this project to cover the extent of a comprehensive program to provide care to postpartum women with OUD who were treated with MAT during pregnancy to improve outcomes for the mother-child dyad. Many opportunities for future research and guideline development exist in reference to prevention, education, and care pathways. A comprehensive guideline should outline processes to provide family-centered care with the goal of improving the mother-child dyad. A program should address outcomes such as bonding of the mother and child, care of the newborn, parenting skills, child well-being and safety, nutrition, and breastfeeding. Research should be conducted that leads to decisions on the development or adoption of checklists to ensure all aspects of care are addressed. Some of these include substance abuse, mental health, post-trauma distress, NAS and neonatal health, intimate

partner or other household member violence, housing, transportation, employment, childcare, and food insecurities. Methods to measure the effectiveness of interventions and assess outcomes should be designed. Ultimately, a formal, comprehensive set of guidelines should be developed to provide a 12-month follow-up program to decrease the rates of relapse in postpartum women with OUD who were treated with MAT during pregnancy and improve the maternal-child bonding process.

Conclusion

This DNP project analyzed the use of an interdisciplinary panel of expert stakeholders to develop a foundational set of guidelines for the care of postpartum women with OUD who were treated with MAT during pregnancy. The goal of the guidelines is to decrease the risk of relapse for the woman and to improve the quality of the mother-child dyad. The methodology of the project incorporated a multistep process including a literature review, grading of evidence, transferring evidence to a decision, formulating a draft of guidelines, presenting the draft to an interdisciplinary panel of experts through a Delphi process for input, draft revision into a final set of guidelines, and presentation of the final guidelines to the expert panel for a consensus vote. Findings of the study revealed that the use of an interdisciplinary panel of experts was a useful tool to gain input and consensus on a practice problem that is best treated with a collaborative multidisciplinary approach.

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Appendix A: Letter of IRB Approval

ABILENE CHRISTIAN UNIVERSITY
Educating Students for Christian Service and Leadership Throughout the World

Office of Research and Sponsored Programs
320 Hardin Administration Building, ACU Box 29103, Abilene, Texas 79699-9103
325-674-2885

July 24, 2020

Lea Ann Quave
Department of Nursing
Abilene Christian University

Dear Lea Ann,

On behalf of the Institutional Review Board, I am pleased to inform you that your project titled "Supporting Postnatal Women with Opioid Use Disorder Treated with Medication Avoidance Therapy",

(IRB# 20-093)is exempt from review under Federal Policy for the Protection of Human Subjects.

If at any time the details of this project change, please resubmit to the IRB so the committee can determine whether or not the exempt status is still applicable.

I wish you well with your work.

Sincerely,

Megan Roth

Megan Roth, Ph.D.
Director of Research and Sponsored Programs

Appendix B: Letter of Support

XXXXXXXXX, BSN, RN
Director of Education
XXXXXXXXXXXXXXXXX
XXXXXXXXXXXX XXXXXX
XXXXXXXXXX

February 3, 2020
To Whom It May Concern:
This letter is written confirmation of intended support for the project proposed by Lea Ann Quave regarding the planning and design of a comprehensive program for postpartum women with opioid use disorder (OUD) who were on medication therapy during pregnancy. I understand that this project will not involve direct patient contact or access to private health information.
XXXXXXXXXXXXX is committed to furthering education and leadership for nurses. It is my pleasure to support this project, which will contribute to research of a growing problem in our community and across the nation, as well as prepare nurses to provide quality care to postpartum women with OUD during a vulnerable time.
I support Ms. Quave in her development of this capstone project to fulfill the requirements of achieving a Doctor of Nursing Practice designation. If you have questions or concerns, please do not hesitate to contact me.
Sincerely,
[redacted]

XXXXXXXXXXXXX, BSN, RN
Director of Education

Appendix C: Informed Consent

Introduction: Supporting Postnatal Women with Opioid Use Disorder Treated with Medication Avoidance Therapy

You may be able to take part in a research study. This form provides important information about that study, including the risks and benefits to you as a potential participant. Please read this form carefully and ask the researcher any questions that you may have about the study. You can ask about research activities and any risks or benefits you may experience. You may also wish to discuss your participation with other people, such as your family doctor or a family member.

Your participation in this research is entirely voluntary. You may refuse to participate or stop your participation at any time and for any reason without any penalty or loss of benefits to which you are otherwise entitled.

PURPOSE & DESCRIPTION: The purpose of this research study is to outline evidence-based contemporary recommendations and define the ideal components of a set of guidelines that could be used to form a program to address the physical, psychosocial, and environmental needs of the mother with opioid use disorder who was treated with medication during pregnancy.

You are being asked to participate in a modified Delphi study, which is a systematic polling of the opinions of an expert panel knowledgeable on a given topic through online surveys in an attempt to reach group consensus on a given topic. You were selected as a possible participant in this study because you have been identified as an experienced practitioner who fills a role in developing or supporting the sobriety and health of women with opioid use disorder who were treated with medication therapy during pregnancy. Through developing a set of guidelines based on expert opinions, it is hoped that a plan to care for women with opioid use disorder who have recently delivered infants can serve as building block for implementing a program design.

If selected for participation, you will be asked to participate in three (3) online sessions provided via email by the study staff over the course of four (4) weeks. The first session is expected to take ten (10) minutes; the second session is expected to take twenty (20) minutes; each subsequent session is expected to take fifteen (15) minutes for a total expected participation time of one (1) hour. During the course of these sessions, you will be asked to participate in the following procedures:

- Session I: Read the recruitment email, access and read this Informed Consent document through the provided hyperlink below, consent to participation in the study by completing the limited demographic data, and clicking the "Yes" option at the end of the consent to advance to the initial page of the survey.
- Session II: You will then be asked to view a short five (5) minute online presentation of the overview of the evidence-based recommendations and complete the Round I Survey as instructed and submit responses to the specified SurveyMonkey website by the designated due date.
- Session III: A approximately one week later, you will receive the Round II survey, which you will be asked to complete according to the Round II Survey instructions and submit to the specified SurveyMonkey website by the designated due date.

- Session IV: Approximately two weeks later, you will receive the Round III Survey, which you will complete according to the Round III Survey instructions and submit this to the specified SurveyMonkey website by the designated due date.

Your responses and information will be encrypted and sent over a secure connection provided by SurveyMonkey. Through an option provided by SurveyMonkey, responses are received anonymously. All respondent information including first name, last name, email address, and IP address are excluded from results.

RISKS & BENEFITS: There are risks to taking part in this research study. Below is a list of the foreseeable risks, including the seriousness of those risks and how likely they are to occur.

The risks associated with participation in this study are minimal and would be rare if they occurred. The primary risk with this study is breach of confidentiality. However, as will be discussed further in the next section, we have taken steps to minimize this risk. If you should feel uncomfortable about participating in the Delphi study, you can discontinue study participation at any time without repercussions by clicking the SurveyMonkey link asking you to be removed from the mailing list. All data collected will be stored in a password-protected computer file in the principal investigator's (PI) office available only to the PI and research staff.

You may not experience any personal benefits from participating in this study.

PRIVACY & CONFIDENTIALITY: Any information you provide will be confidential to the extent allowable by law. Your confidentiality will be protected by ensuring that there will be no identifying information on any of the data from the Delphi study. Your survey submission will be associated with your email address, which will be kept in a log that will be stored in a password-protected computer file available only to the researcher. You will need to be contacted by the researcher via your email address during the study if you do not respond during the requested time frame between each Delphi round. Some identifiable data may have to be shared with individuals outside of the study team, such as members of the ACU Institutional Review Board. Otherwise, your confidentiality will be protected. All data collected during the process of project implementation and analysis will be stored as de-identified data. The data will be stored in a secure Google drive provided by ACU under the researcher's name. Data will become the property of the university in case access is needed at a future date. This drive storage system will be provided by the online graduate school for doctoral student research data and supported by the university's IT department for security purposes. It will be kept for the minimum required time according to IRB guidelines.

The primary risk with this study is breach of confidentiality. However, we have taken steps to minimize this risk. We will not be collecting any personal identification data during the survey. However, SurveyMonkey may collect information from your computer. You may read their privacy statements here: https://www.surveymonkey.com/mp/policy/privacy-policy/.

CONTACTS: If you have questions about the research study, the lead researcher is Lea Ann Quave, MSN, RN, and may be contacted at XXXXXXX XXXXXXXXXand/or XXXXXXXXXX XXXXXXXXXX. If you are unable to reach the lead researcher, or wish to speak to someone other than the lead researcher, you may contact xxx xxxxx, DrPH, MPA, MSN, RN, XXXXXXXXX, XXXXXXXXXX.

If you have concerns about this study, believe you may have been injured because of this study, or have general questions about your rights as a research participant, you may contact ACU's Chair of the Institutional Review Board and Executive Director of Research, Mxxxx Rxxx, Ph.D. Dr. Rxxx may be reached at

Additional Information

The expected number of participants to be enrolled in this study is seven (7) to ten (10).

Your participation may be ended early by the researchers for certain reasons. For example, we may end your participation if you no longer meet study requirements, the researchers believe it is no longer in your best interest to continue participating, you do not follow the instructions provided by the researchers, or the study is ended. You will be contacted by the researchers and given further instructions in the event that you are removed from the study.

Consent Signature Section

For electronic consent to complete online surveys: **Do you consent to participation in this study?** Please answer the question by clicking the Yes button below to agree to the terms of this consent, or the No button below to decline participation. If you click Yes, you will be asked to you enter your last name, email address and professional designation. Click Yes only after you have read all of the information provided and your questions have been answered to your satisfaction. If you wish to have a copy of this consent form, you may print it now. You do not waive any legal rights by consenting to this study.

If you would like to decline participation in this study, please do so by clicking the No button to terminate this request for consent.

Appendix D: PWOUD Checklist (Delphi Round I)

PWOUD Rating of Clinical Practice Guidelines

Rating Scale: (7) Strongly Agree, (6) Agree, (5) Partially Agree, (4) Neutral, (3) Partially Disagree, (2) Disagree, (1) Strongly Disagree

Domain	SA	A	PA	N	PD	D	SD	N/A
1. The overall objective of the guideline is specifically described								
2. The health question covered by the guideline is specifically described								
3. The population to whom the guideline is meant to apply is specifically described								
4. The guideline development group includes individuals from all the relevant professional groups								
5. The views and preferences of the target population have been sought								
6. The target uses of the guidelines are clearly defined								
7. Systematic methods were used to search for evidence								
8. The criteria for selecting the evidence are clearly described								
9. The strengths and limitations of the body of evidence are clearly described								
10. The methods for formulating the recommendations are clearly described								
11. The health benefits, side effects, and risks have been considered in formulating the recommendations								
12. There is an explicit link between the recommendations and the supporting evidence								
13. The guideline has been externally reviewed by experts prior to its publication								
14. A procedure for updating the guideline is provided								
15. The recommendations are specific and unambiguous								
16. The different options for the management of the condition or health issue are clearly presented								
17. Key recommendations are easily identifiable								
18. The guidelines provide advice and/or tools on how the recommendations can be put into practice								
19. The guidelines describe facilitators and barriers to its application								
20. The potential resource implications of applying the recommendations has been considered								
21. The guidelines present monitoring and/or auditing criteria								
22. The views of the funding body have not influenced the content of the guideline								
23. Competing interests of guideline development group members have been recorded and addressed								

Comments:

Adapted from “AGREE II: Advancing Guideline Development, Reporting and Evaluation in Healthcare,” by M. C. Brouwers, M. E. Kho, G. P. Browman, F. Cluzeau, G. Feder, B. Fervers, S. Hanna, J. Makarski on behalf of the AGREE Next Steps Consortium, 2010, *Canadian Medical Association Journal*, *182*, E839-842. Copyright 2010-2014 by The AGREE Research Trust.

Appendix E: PWOUDChecklist (Final Round)

PWOUDRating of Clinical Guidelines

Domain	Item	PWOUDRating						
		1 *Strongly Disagree*	**2**	**3**	**4**	**5**	**6**	**7** *Strongly Agree*
Scope and purpose	1. The overall objective(s) of the guideline is (are) specifically described.							
	2. The health question(s) covered by the guideline is (are) specifically described.							
	3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.							
Stakeholder involvement	4. The guideline development group includes individuals from all the relevant professional groups.							
	5. The views and preferences of the target population (patients, public, etc.) have been sought.							
	6. The target users of the guideline are clearly defined.							
Rigor of development	7. Systematic methods were used to search for evidence.							
	8. The criteria for selecting the evidence are clearly described.							
	9. The strengths and limitations of the body of evidence are clearly described.							
	10. The methods for formulating the recommendations are clearly described.							
	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.							
	12. There is an explicit link between the recommendations and the supporting evidence.							
	13. The guideline has been externally reviewed by experts prior to its publication.							
	14. A procedure for updating the guideline is provided.							
Clarity of presentation	15. The recommendations are specific and unambiguous.							
	16. The different options for management of the condition or health issue are clearly presented.							
	17. Key recommendations are easily identifiable.							
Applicability	18. The guideline describes facilitators and barriers to its application.							
	19. The guideline provides advice and/or tools on how the recommendations can be put into practice.							
	20. The potential resource implications of applying the recommendations have been considered.							
	21. The guideline presents monitoring and/or auditing criteria.							
Editorial independence	22. The views of the funding body have not influenced the content of the guideline.							
	23. Competing interests of guideline development group members have been recorded and addressed.							
Overall Guideline Assessment	1. Rate the overall quality of this guideline.	**1** *Lowest possible quality*	**2**	**3**	**4**	**5**	**6**	**7** *Highest possible quality*
Overall Guideline Assessment	2. I would recommend this guideline for use.	*Yes*	*Yes, with modifications*					*No*

Adapted from “AGREE II: Advancing Guideline Development, Reporting and Evaluation in Healthcare,” by M. C. Brouwers, M. E. Kho, G. P. Browman, F. Cluzeau, G. Feder, B. Fervers, S. Hanna, J. Makarski on behalf of the AGREE Next Steps Consortium, 2010, Canadian Medical Association Journal, 182, E839-842. Copyright 2010-2014 by The AGREE Research Trust.

Appendix F: Project Timeline

Task	Year	Month
Secure clinical site	2018	August
Compose draft of Chapters 1, 2, 3	2018	Sept–Dec
Compose draft of Chapters 1, 2, 3	2019	Jan–Dec
Complete first public defense	2020	March
Begin literature review	2020	March–May
Obtain IRB approval for project from ACU and project site	2020	April
Present to GRADE and EtD framework findings to interdisciplinary panel of stakeholders	2020	June
Develop formal guidelines	2020	June–August
Present formal guidelines to interdisciplinary panel of stakeholders	2020	August
Complete 4th and 5th chapters	2020	June–Sept
Schedule final defense	2020	October

Appendix G: Recruitment Email

Greetings:

As a component of completion of a Doctor of Nursing Practice (DNP) program at the Abilene Christian University, I will be implementing a DNP project to address a particular practice problem. With an increase in the number of pregnant women in our community on the Texas Gulf Coast presenting with opioid use disorder (OUD) and treatment with medication avoidance therapy (MAT) during pregnancy, a need has been identified to reframe interventions to improve follow up in the postpartum period to decrease the risk for recidivism and relapse. The purpose of this scholarly DNP nonexperimental prospective exploratory project is to utilize best evidence-based literature, professional guidelines and theoretical models for the design of a comprehensive postnatal program for this population. The program design uses an online-modified Delphi format to collect data from an expert panel. You are being asked to participate in this Delphi study in an attempt to reach group consensus on a set of guidelines to structure care for this population. You were selected as a possible participant in this study because you have been identified as an experienced practitioner who fills a role in developing or supporting the sobriety and health of women with opioid use disorder who were treated with medication therapy during pregnancy.

The project will begin with a systematic literature review from quantitative and qualitative evidence-based literature to format a set of formal guidelines for the care of a vulnerable population. The project will also include use of the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system of appraisal and the GRADE Evidence to Decision (EtD) framework to synthesize the evidence and form recommendations for a comprehensive postnatal follow-up program for women with OUD who were treated with MAT during pregnancy. Using an online Delphi survey through SurveyMonkey, the compilation of evidence and recommendations will then be presented to a panel of interdisciplinary stakeholders from the community in the Texas Gulf Coast region that has seen an increase in pregnant women with OUD who are being treated during pregnancy for their input and consensus. This program can provide a structure and process for implementing best practice clinical guidelines for the management and support of the postpartum mother-child dyad.

If you volunteer to participate in this Delphi study, you will be asked to do the following:

- Session I: Read this recruitment email and the provided Informed Consent document, consent to data collection by clicking to advance the page to the survey, and complete the limited demographic data. Time commitment is expected to be approximately 10 minutes.
- Session II: You will then be asked to view a short five (5) minute online presentation of the overview of the evidence-based recommendations and complete the Round I Survey as instructed and submit responses to the specified SurveyMonkey website by the designated due date. Time commitment is expected to be approximately 20 minutes.
- Session III: Approximately one week later, you will receive the Round II Survey, which you will be asked to complete according to the Round II Survey instructions and submit

to the specified SurveyMonkey website by the designated due date. Time commitment is expected to be approximately 15 minutes.

- Session IV: Approximately two weeks later, you will receive the Round III Survey, which you will complete according to the Round III Survey instructions and submit this to the specified SurveyMonkey website by the designated due date. Time commitment is expected to be approximately 15 minutes.

Time Commitment: Overall, participation in the Delphi study will take approximately one hour.

If you have questions about the research study, please contact me as the DNP student.

Lea Ann Quave, MSN, RN
XXXXXXXXX
XXXXXXXXXXXXX
XXXXXX XXXXXXX XXXXXXXXX

Appendix H: Permission to Conduct Research Using SurveyMonkey

SurveyMonkey Inc.
www.surveymonkey.com

For questions, visit our Help Center
help.surveymonkey.com

Re: Permission to Conduct Research Using SurveyMonkey

To Whom It May Concern:

This letter is being produced in response to a request by a student at your institution who wishes to conduct a survey using SurveyMonkey in order to support their research. The student has indicated that they require a letter from SurveyMonkey granting them permission to do this. Please accept this letter as evidence of such permission. Students are permitted to conduct research via the SurveyMonkey platform provided that they abide by our Terms of Use at https://www.surveymonkey.com/mp/legal/terms-of-use/.

SurveyMonkey is a self-serve survey platform on which our users can, by themselves, create, deploy, and analyze surveys through an online interface. We have users in many different industries who use surveys for many different purposes. One of our most common use cases is students and other types of researchers using our online tools to conduct academic research.

If you have any questions about this letter, please contact us through our Help Center at help.surveymonkey.com.

Sincerely,

SurveyMonkey Inc.

Appendix I: Secondary Literature Review

Literature Review of Best Evidence Interventions for Postpartum Women with Opioid Use Disorder Treated with Medication Avoidance Therapy During Pregnancy

The goal of this rapid literature review is to organize evidence to support the findings of a previously completed systematic literature review to determine best evidence-based practice for the follow-up care of postpartum women with opioid use disorder (OUD) who were treated with medication avoidance therapy (MAT) during pregnancy. The evidence was supported by a review of existing guidelines from various like-minded organizations providing care to the target population. The question guiding this literature review was: What main interventions should form the basis of a guideline for the care of postpartum women with OUD who were treated with MAT during pregnancy after they are released from the hospital, and what will help them remain abstinent and on the road to recovery? The results of all the reviewed articles and guidelines showed the top three best evidence-based practice interventions with good results were collaborative multidisciplinary management, in-home visits, and assessment checklists to guide care.

Methodology

A literature review was completed using the online EBSCOhost database provided through the Margarett and Herman Brown Library at Abilene Christian University. The following terms were used for the initial search: postpartum, home visits “or” checklist “or” multidisciplinary team, opioid, relapse. Filters used were full text, scholarly peer reviewed journal articles, academic journals, substance abuse, and pregnancy. Publications between the years 2015 and 2020 were included. The initial search produced 9,729 results. After filters were

added, 31 articles remained. Duplicate articles were excluded, as were articles published in countries other than the United States and articles that did not provide relevant information; 13 articles remained and were included in the review.

Review of Literature

Collaborative multidisciplinary management. Collaborative care of the postpartum women with OUD must address physical, psychological, and socioeconomic issues such as postnatal health care for the mother and infant, substance use, pharmacological MAT adherence, housing instability, food insecurity, intimate partner violence, mother-child bonding, and mental health disorders (Hanson, Saul, Duryea et al., 2019; Hanson, Saul, Vanderploeg et al., 2015; Harvey et al., 2015; Higgins et al., 2019; Hodgins et al., 2019). Goodman et al. (2015) found that better outcomes where achieved when care for mothers with substance abuse were treated in a multidisciplinary manner which included women's health care, addiction therapy, health promotion for mother and child, and education to meet the learning needs of the mother. In addition to collaborative management of the mother, interdisciplinary team care for the infant with neonatal abstinence syndrome, or the infant with a propensity for complications of maternal opioid use, has shown to improve health outcomes (Anbalagan & Mendez, 2020). Social services and family counselors on the collaborative care team provide resource allocation to match client needs, as well as parenting education that can motivate the postpartum woman to remain sober (Holbrook & Nguyen, 2015). Increased involvement of social service and child welfare should be initiated for children at risk (Holbrook & Nguyen, 2015).

In-home visits. Home visits allow the health care team to "meet women where they are" (Hodgins et al., 2019, p. 586). The Collaborative Outreach and Adaptable Care at Hallmark Health (COACHH) program in Massachusetts has found check-ins one or two times a week

through home visits or phone calls to improve outcomes for mothers with substance use disorder (Hodgins et al., 2019). The home visits allow the provider to assess the home environment and gain a glimpse of the everyday life of the client to facilitate care based on observation (Hodgins et al., 2019; Lewis et al., 2017). The Johns Hopkins University family-based recovery model (FBR) successfully helps mothers with OUD to remain sober by implementing a series of step-down home visits; the client is seen in their home at three separate 60-minute visits for the six months of treatment, tapering to once a week visits by the end of the first year postpartum (Hanson, Saul, & Duryea et al., 2019). Home visits were found to decrease risk of relapse, increase treatment retention, improve parenting skills of the mother, decrease adverse involvement of child welfare departments, and reduce subsequent unintended short interval pregnancies in postpartum women with OUD (Goodman et al., 2015). Home visits can be supplemented with technology such as smartphones, which have been provided to clients to facilitate check-ins, send reminders of appointments, complete surveys, provide education, and facilitate communication (Sanjuan et al., 2020).

Assessment checklists. An integrated needs assessment has been shown to improve outcomes for the mother-child dyad (Hodgins et al., 2019). Ongoing assessment through documentation, such as a checklist, provides a means for measuring improvement or reveal downward trends; thus, improving outcomes for postpartum women with OUD (Goodman et al., 2019; Hodgins et al., 2019). Following a standardized checklist can prevent the oversight of important assessments and improve communication of needs to other members of the healthcare team (Goodman et al., 2019). Items that assess anxiety and stress of the mother should be included in the checklist since high-stress situations can lead to relapse (Dworkin et al., 2017; Fallin-Bennett et al., 2020; Hanson, Saul & Duryea et al., 2019; Hanson, Saul, & Vanderploeg et

al., 2015; Harvey et al., 2015). Mother-child bonding and attachment are important indicators of family dynamics; lack of a healthy mother-child relationship may indicate psychological issues that could lead to relapse and should therefore be a routine assessment measure (Hanson, Saul, & Duryea et al., 2019; Hanson, Saul, & Vanderploeg et al., 2015; Mirick & Steenrod, 2016; Sanjuan et al., 2020). Socioeconomic assessment should be included in the checklist, such as lack of transportation, unsafe housing, and food insecurities (Lewis et al., 2017). Postpartum women with OUD should be assessed for alcohol, tobacco, and other substance use, partner violence, food insecurities, housing and food insecurity, mental health disorders such as postpartum depression, and anxiety (Fallin-Bennett et al., 2020; Higgins et al., 2019). Topics that should be incorporated into the checklist include home safety, housing stability, open-communication link, home security, and interactions between mother and other members of the household (Goodman et al., 2019). The visit should include a socioeconomic checklist, an opioid use questionnaire, and a maternal-child teaching assessment tool (Goodman et al., 2019). One of the many tools to assess for NAS symptoms or complications of maternal opioid use can be used for months after birth and should be part of the home visit assessment (Anbalagan & Mendez, 2020).

Summary and Recommendations

In summary, the literature did show that group support through multidisciplinary care teams, home visits, and an assessment checklist are essential for mother-child well-being. It is recommended that these three interventions be submitted for initial guideline development of a program for postpartum women with OUD who were treated with MAT during pregnancy.

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Appendix J: GRADE Table of Evidence

Author(s): Lea Ann Quave, MSN-Ed, RN
Question: Should best evidence-based interventions be used to create a guideline compared to not using best evidence-based interventions to create a guideline to help reduce relapse and improve the mother-child dyad for postpartum women with OUD who were treated with MAT during pregnancy? What main interventions should form the basis of a guideline for the care of postpartum women with OUD who were treated with MAT during pregnancy after they are released from the hospital, and what will help them stay clean and sober and on the road to recovery?
Setting: rural community in Texas Gulf Coast

Certainty assessment							Impact	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
Home visits will help reduce relapse and improve the mother-child dyad.									
9	observational studies	not serious [a]	not serious	not serious	not serious	none	Home visits allow the health care team to "meet women where they are" (Hodgins et al., 2019, p. 586). The Collaborative Outreach and Adaptable Care at Hallmark Health (COACHH) program in Massachusetts has found check-ins one or two times a week through home visits or phone calls to improve outcomes for mothers with substance use disorder (Hodgins et al., 2019). The home visits allow the provider to assess the home environment and gain a glimpse of the everyday life of the client to facilitate care based on observation (Hodgins et al., 2019; Lewis et al., 2017). The Johns Hopkins University family-based recovery model (FBR) successfully helps mothers with OUD to remain sober by implementing a series of step-down home visits; the client is seen in their home at three separate 60-minute visits for the six months of treatment, tapering to once a week visits by the end of the first year postpartum (Hanson, Saul, & Duryea et al., 2019). Home visits were found to decrease risk of relapse, increase treatment retention, improve parenting skills of the mother, decrease adverse involvement of child welfare departments, and reduce subsequent unintended short interval pregnancies in postpartum women with OUD (Goodman et al., 2015). Home visits can be supplemented with technology such as smartphones, which have been provided to clients to facilitate check-ins, send reminders of appointments, complete surveys, provide education, and facilitate communication (Sanjuan et al., 2020).	⨁⨁◯◯ LOW [b]	CRITICAL

Certainty assessment							Impact	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
A visit checklist used by the care professional will help reduce relapse and improve the mother-child dyad.									
10	observational studies	not serious [a]	not serious	not serious	not serious	none	An integrated needs assessment has been shown to improve outcomes for the mother-child dyad (Hodgins et al., 2019). Ongoing assessment through documentation, such as a checklist, provides a means for measuring improvement or reveal downward trends; thus, improving outcomes for postpartum women with OUD (Goodman et al., 2019; Hodgins et al., 2019). Following a standardized checklist can prevent the oversight of important assessments and improve communication of needs to other members of the healthcare team (Goodman et al., 2019). Items that assess anxiety and stress of the mother should be included in the checklist since high stress situations can lead to relapse (Dworkin et al., 2017; Fallin-Bennett et al., 2020; Hanson, Saul & Duryea et al., 2019; Hanson, Saul, & Vanderploeg et al., 2015; Harvey et al., 2015). Mother-child bonding and attachment are important indicators of family dynamics; lack of a healthy mother-child relationship may indicate psychological issues that could lead to relapse and should therefore be a routine assessment measure (Hanson, Saul, & Duryea et al., 2019; Hanson, Saul, & Vanderploeg et al., 2015; Mirick & Steenrod, 2016; Sanjuan et al., 2020). Socioeconomic assessment should be included in the checklist, such as lack of transportation, unsafe housing, and food insecurities (Lewis et al., 2017). Postpartum women with OUD should be assessed for alcohol, tobacco, and other substance use, partner violence, food insecurities, housing and food insecurity, mental health disorders such as postpartum depression, and anxiety (Fallin-Bennett et al., 2020; Higgins et al., 2019). Topics that should be incorporated into the checklist include home safety, housing stability, open-communication link, home security, and interactions between mother and other members of the household (Goodman et al., 2019). The visit should include a socioeconomic checklist, an opioid use questionnaire, and a maternal-child teaching assessment tool (Goodman et al., 2019). One of the many tools to assess for NAS symptoms or complications of maternal opioid use can be used for months after birth and should be part of the home visit assessment (Anbalagan & Mendez, 2020).	⨁⨁◯◯ LOW [b]	CRITICAL

Certainty assessment							Impact	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
A multidisciplinary team approach will help reduce relapse and improve the mother-child dyad.									
11	observational studies	not serious [a]	not serious	not serious	not serious	none	Collaborative care of the postpartum women with OUD must address physical, psychological, and socioeconomic issues such as postnatal health care for the mother and infant, substance use, pharmacological MAT adherence, housing instability, food insecurity, intimate partner violence, mother-child bonding, and mental health disorders (Hanson, Saul, & Duryea et al., 2019; Hanson, Saul, & Vanderploeg et al., 2015; Harvey et al., 2015; Higgins et al., 2019; Hodgins et al., 2019). Goodman et al. (2015) found that better outcomes where achieved when care for mothers with substance abuse were treated in a multidisciplinary manner which included women's health care, addiction therapy, health promotion for mother and child, and education to meet the learning needs of the mother. In addition to collaborative management of the mother, interdisciplinary team care for the infant with neonatal abstinence syndrome, or the infant with a propensity for complications of maternal opioid use, has shown to improve health outcomes (Anbalagan & Mendez, 2020). Social services and family counselors on the collaborative care team provide resource allocation to match client needs, as well as parenting education that can motivate the postpartum woman to remain sober (Holbrook & Nguyen, 2015). Increased involvement of social service and child welfare should be initiated for children at risk (Holbrook & Nguyen, 2015).	⨁⨁◯◯ LOW [b]	CRITICAL

CI: Confidence interval

Explanations

a. Bias is difficult to ascertain in observational studies researching mental health or population health.
b. Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Appendix K: Clinical Practice Guidelines Evidence to Decision (EtD) Framework

CLINICAL PRACTICE GUIDELINES EVIDENCE TO DECISION (EtD) RECOMMENDATIONS FOR PWOUD CHECKLIST
Domain: Scope and purpose *The overall objective of the initial guideline is to use three main best evidence-based practice interventions as the foundation to construct comprehensive guidelines for a 12-month follow-up program for the care of postpartum women with opioid use disorder (OUD) who were treated with medication assisted treatment (MAT) during pregnancy. It has been shown that mothers who use opioids are less likely to develop healthy attachment relationships with infants and children, leading to an increase in behavioral and emotional issues for the child that can have long-lasting effects (Romanowicz et al., 2019). The overarching goal of the program will be to decrease the rate of relapse in postpartum women and improve the parental relationship between the mother and child. The question guiding this program design project is as follows: Will the use of an interprofessional multidisciplinary team, home visits, and the use of standardized checklists provide a sufficient foundation to facilitate the development of clinical practice guidelines for a postpartum follow-up program for women treated for opioid use disorder during pregnancy with MAT? The comprehensive program guidelines will be used to provide care to postpartum women with OUD who were treated with MAT during pregnancy in a rural community on the Texas Gulf Coast.* **PWOUD Checklist Items:** 1. The overall objective(s) of the guideline is (are) specifically described. 2. The health question(s) covered by the guideline is (are) specifically described. 3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.
Domain: Stakeholder involvement *The guideline development group includes an anonymous panel of experts from multiple disciplines that hold an interest in the care of the target population. Panel members include professionals in the following specialties: mental health, addiction services, registered nurse leadership, social work, women's health, pediatrics, and community services. The views of the guideline development group will be sought during the guideline development process. The views of the ultimate target population, postpartum women with OUD who were treated with MAT during pregnancy, were evaluated during the review of the evidence; views and preferences of the target population will be sought during implementation of the following comprehensive program design.* **PWOUD Checklist Items:** 4. The guideline development group includes individuals from all the relevant professional groups. 5. The views and preferences of the target population (patients, public, etc.) have been sought. 6. The target users of the guideline are clearly defined.

Domain: Rigor of development

A rapid review literature review was completed using the online EBSCOhost database provided through the Margarett and Herman Brown Library at Abilene Christian University. Rapid reviews are endorsed by the World Health Organization (WHO) and are well-suited for time sensitive tasks such as guideline development and decision-making regarding recommendations as they provide concise and focused information on relevant topics and are intended to address specific end-users rather than contribute to general knowledge (Hartling et al., 2017; Hartling et al., 2015; Langlois et al., 2018; Tricco et al., 2017). The goal of this rapid literature review is to organize evidence to support the findings of a previously completed systematic literature review to determine best evidence-based practice for the follow-up care of postpartum women with opioid use disorder (OUD) who were treated with MAT during pregnancy. The evidence was supported by a review of existing guidelines from various like-minded organizations providing care to the target population. The question guiding this literature review was: What main interventions should form the basis of a guideline for the care of postpartum women with OUD who were treated with MAT during pregnancy after they are released from the hospital, and what will help them remain abstinent and on the road to recovery?
The following terms were used for the initial search: postpartum, home visits "or" checklist "or" multidisciplinary team, opioid, relapse. Filters used were full text, scholarly peer reviewed journal articles, academic journals, substance abuse, and pregnancy. Publications between the years 2015 and 2020 were included. The initial search produced 9,729 results. After filters were added, 31 articles remained. Duplicate articles were excluded, as were articles published in countries other than the United States and articles that did not provide relevant information; 13 articles remained and were included in the review.

Review of Literature. Collaborative multidisciplinary management. *Collaborative care of the postpartum women with OUD must address physical, psychological, and socioeconomic issues such as postnatal health care for the mother and infant, substance use, pharmacological MAT adherence, housing instability, food insecurity, intimate partner violence, mother-child bonding, and mental health disorders (Hanson, Saul, & Duryea et al., 2019; Hanson, Saul, & Vanderploeg et al., 2015; Harvey et al., 2015; Higgins et al., 2019; Hodgins et al., 2019). Goodman et al. (2015) found that better outcomes where achieved when care for mothers with substance abuse were treated in a multidisciplinary manner which included women's health care, addiction therapy, health promotion for mother and child, and education to meet the learning needs of the mother. In addition to collaborative management of the mother, interdisciplinary team care for the infant with neonatal abstinence syndrome, or the infant with a propensity for complications of maternal opioid use, has shown to improve health outcomes (Anbalagan & Mendez, 2020). Social services and family counselors on the collaborative care team provide resource allocation to match client needs, as well as parenting education that can motivate the postpartum woman to remain sober (Holbrook & Nguyen, 2015). Increased involvement of social service and child welfare should be initiated for children at risk (Holbrook & Nguyen, 2015).*
In-home visits. *Home visits allow the health care team to "meet women where they are" (Hodgins et al., 2019, p. 586). The Collaborative Outreach and Adaptable Care at Hallmark Health (COACHH) program in Massachusetts has found check-ins one or two times a week through home visits or phone calls to improve outcomes for mothers with substance use disorder (Hodgins et al., 2019). The home visits allow the provider to assess the home environment and gain a glimpse of the everyday life of the client to facilitate care based on observation (Hodgins et al., 2019; Lewis*

et al., 2017). The Johns Hopkins University family-based recovery model (FBR) successfully helps mothers with OUD to remain sober by implementing a series of step-down home visits; the client is seen in their home at three separate 60-minute visits for the six months of treatment, tapering to once a week visits by the end of the first year postpartum (Hanson, Saul, & Duryea et al., 2019). Home visits were found to decrease risk of relapse, increase treatment retention, improve parenting skills of the mother, decrease adverse involvement of child welfare departments, and reduce subsequent unintended short interval pregnancies in postpartum women with OUD (Goodman et al., 2015). Home visits can be supplemented with technology such as smartphones, which have been provided to clients to facilitate check-ins, send reminders of appointments, complete surveys, provide education, and facilitate communication (Sanjuan et al., 2020).

Assessment checklists. *An integrated needs assessment has been shown to improve outcomes for the mother-child dyad (Hodgins et al., 2019). Ongoing assessment through documentation, such as a checklist, provides a means for measuring improvement or reveal downward trends; thus, improving outcomes for postpartum women with OUD (Goodman et al., 2019; Hodgins et al., 2019). Following a standardized checklist can prevent the oversight of important assessments and improve communication of needs to other members of the healthcare team (Goodman et al., 2019). Items that assess anxiety and stress of the mother should be included in the checklist since high-stress situations can lead to relapse (Dworkin et al., 2017; Fallin-Bennett et al., 2020; Hanson, Saul & Duryea et al., 2019; Hanson, Saul, & Vanderploeg et al., 2015; Harvey et al., 2015). Mother-child bonding and attachment are important indicators of family dynamics; lack of a healthy mother-child relationship may indicate psychological issues that could lead to relapse and should therefore be a routine assessment measure (Hanson, Saul, & Duryea et al., 2019; Hanson, Saul, & Vanderploeg et al., 2015; Mirick & Steenrod, 2016; Sanjuan et al., 2020). Socioeconomic assessment should be included in the checklist, such as lack of transportation, unsafe housing, and food insecurities (Lewis et al., 2017). Postpartum women with OUD should be assessed for alcohol, tobacco, and other substance use, partner violence, food insecurities, housing and food insecurity, mental health disorders such as postpartum depression, and anxiety (Fallin-Bennett et al., 2020; Higgins et al., 2019). Topics that should be incorporated into the checklist include home safety, housing stability, open-communication link, home security, and interactions between mother and other members of the household (Goodman et al., 2019). The visit should include a socioeconomic checklist, an opioid use questionnaire, and a maternal-child teaching assessment tool (Goodman et al., 2019). One of the many tools to assess for NAS symptoms or complications of maternal opioid use can be used for months after birth and should be part should be a part of the home visit assessment (Anbalagan & Mendez, 2020).*

This guideline has been reviewed by the author and is being presented for review by an expert panel of stakeholders. This presentation is the initial review of the guideline. The guideline will be updated throughout the review process based on recommendations by the expert panel. Once consensus on acceptance of the guideline has been reached, it will be used as the basis of a formal, comprehensive guideline development project for a program to treat the target population.

PWOUDChecklist Items:

7. Systematic methods were used to search for evidence.
8. The criteria for selecting the evidence are clearly described.
9. The strengths and limitations of the body of evidence are clearly described.
10. The methods for formulating the recommendations are clearly described.

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.
12. There is an explicit link between the recommendations and the supporting evidence.
13. The guideline has been externally reviewed by experts prior to its publication.
14. A procedure for updating the guideline is provided.

Domain: Clarity of presentation

The results of all the reviewed articles and guidelines showed the top three best evidence-based practice interventions with good results were collaborative multidisciplinary management, in-home visits, and assessment checklists to guide care. In summary, the literature did show that group support through multidisciplinary care teams, home visits, and an assessment checklist are essential for mother-child well-being. It is recommended that these three interventions be submitted for initial guideline development of a program for postpartum women with OUD who were treated with MAT during pregnancy.

PWOUD Checklist Items:

15. The recommendations are specific and unambiguous.
16. The different options for management of the condition or health issue are clearly presented.
17. Key recommendations are easily identifiable.

Domain: Applicability

Items in the domain of applicability are not addressed in this guideline. Applicability items will be addressed during the development of a formal, comprehensive guideline development project for a program to treat the target population.

PWOUD Checklist Items (will be graded as neutral on checklist)**:**

18. The guideline describes facilitators and barriers to its application.
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.
20. The potential resource implications of applying the recommendations have been considered.
21. The guideline presents monitoring and/or auditing criteria.

Domain: Editorial independence

There were no funding bodies for this guideline development. There were no competing interests between guideline development group members.

PWOUDChecklist Items:

22. The views of the funding body have not influenced the content of the guideline.
23. Competing interests of guideline development group members have been recorded and addressed.