

Implementing Breastfeeding Education into a Perinatal Medication Assisted Recovery Program

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Abstract

Opioid use disorder (OUD) is a chronic, complex health condition that continues to be a growing problem in the general population, and this increase is paralleled in pregnant women. Pregnancy is a time when women with OUD may be ready to begin a journey of recovery. OUD has both maternal and fetal implications. The safest way to begin recovery during pregnancy is with the initiation of either buprenorphine or methadone to prevent symptoms of withdrawal which can increase risk of fetal harm. Both medications have the added benefit of being safe to use during lactation. There is a minimal amount of either medication that is found in breastmilk.

Breastfeeding during medication assisted recovery (MAR) is linked both to improved maternal and neonatal outcomes, and improved bonding. Often women who are engaged in MAR are unaware of the benefits of breastfeeding initiation and exclusivity. Mothers may perceive breastfeeding as a danger to their baby based on misinformation and bias. Initiation of individualized and nonjudgmental breastfeeding education to women beginning an inpatient MAR program can improve maternal understanding of the benefits of exclusive breastfeeding and increase intention to exclusively breastfeed.

Keywords: medication assisted recovery, opioid misuse disorder, breastfeeding intention, breastfeeding education.

Implementing Breastfeeding Education into a Perinatal Medication Assisted Recovery Program

Opioid use disorder (OUD) is a chronic and complex condition that continues to be a growing problem in Arizona and the United States (Arizona Department of Health Services [AZDHS], 2019; Centers for Disease Control & Prevention [CDC], 2018). The number of pregnant women using opioids during their pregnancy across the nation has continued to increase (American College of Obstetricians & Gynecologists [ACOG], 2017; CDC, 2018; McGlothen, Cleveland, & Gill, 2018; Smith & Lipari, 2017). Opioid detoxification during pregnancy is not recommended due to increased risk of fetal harm (ACOG, 2017; Cleveland, 2016, Ecker et al., 2019; McLafferty et al., 2016). Medication assisted recovery (MAR) with either methadone or buprenorphine, is the standard recommendation for OUD during pregnancy to decrease fetal risks and improve both maternal and fetal outcomes. Breastfeeding is recommended for women engaged in MAR, and has both maternal and infant benefits (ACOG, 2017; Cleveland, 2016; Ecker et al., 2019; Hicks, Morse, & Wyant, 2018; McLafferty et al., 2016; Reece-Stremtan, Marinelli, & the Academy of Breastfeeding Medicine [ABM]; 2015; Tsai & Doan, 2016).

Problem Statement

Breastfeeding is recommended for mothers participating in MAR if certain conditions are met. She should be on stable doses of methadone or buprenorphine, in a treatment program, not using other substances, and have no other existing contraindications to breastfeeding (ACOG, 2017; Cleveland, 2016; Ecker et al., 2019; Hicks, Morse, & Wyant, 2018; Reece-Stremtan, Marinelli, & ABM, 2015). Contraindications to breastfeeding include use of other illicit drugs, including marijuana, and human immunodeficiency virus (HIV) positive status. While there are many benefits to breastfeeding when engaged in MAR, this population generally has a low rate of breastfeeding initiation and continuation (Demirci, Bogen, & Klionsky, 2015; Holmes,

Schmidlen, & Kurzum, 2017; MacVicar, Humphrey, & Forbes-McKay, 2017; McGlothen, Cleveland, & Gill, 2018; Tsai & Doan, 2016; Wachman et al., 2016; Yonke, Maston, Weitzen, & Leeman, 2019). Breastfeeding barriers may be personal, societal or systemic. Barriers may include a history of abuse or trauma, low self-esteem, maternal lack of education and actual or perceived lack of support (Demirci, Bogen & Klionsky, 2015; Hicks, Morse, & Wyant, 2018; Holmes, Schmidlin, & Kurzum, 2017; MacVicar, Humphrey, & Forbes-McKay, 2017; McGlothen, Cleveland, & Gill, 2018; Tsai & Doan, 2016; Wachman et al., 2016). Barriers may also result from provider prejudice and lack of education, as well as institutional policies and procedures that are not supportive of breastfeeding or result in extended periods of maternal infant separation (Demirci, Bogen & Klionsky, 2015; Hicks, Morse, & Wyant, 2018; Holmes, Schmidlin, & Kurzum, 2017; MacVicar, Humphrey, & Forbes-McKay, 2017; McGlothen, Cleveland, & Gill, 2018; Tsai & Doan, 2016; Wachman et al., 2016).

The standard for treatment of OUD in pregnancy is MAR with either methadone or buprenorphine (ACOG, 2017; Ecker et al., 2019; SAMSHA, 2015, 2016, 2018; WHO, 2014). Both medications have been shown to decrease the risk of relapse at an appropriate dose. The goal of treatment is to relieve symptoms of withdrawal and reduce cravings. Stable dosing decreases serum peaks and troughs that expose the infant to repeated withdrawals. MAR used in conjunction with comprehensive care for treatment of perinatal OUD has demonstrated decreased pregnancy complications, increased birth weights, reduction in risky behaviors, increased compliance with prenatal care and addiction treatment (ACOG, 2017; Ecker et al., 2019; SAMSHA, 2018). Medications should be offered in conjunction with counseling for best outcomes (ACOG, 2017; Ecker et al., 2019; McLafferty et al., 2016; SAMSHA, 2018). Treatment options should be individualized to the patient's current needs.

Methadone and buprenorphine are found in minimal amounts in breastmilk (ACOG, 2017; Cleveland, 2016; Ecker et al., 2019; Hicks, Morse, & Wyant, 2018; Ito, 2018; Reece-Stremtan, Marinelli, & ABM, 2015; Wachman et al., 2016; Wu & Carre, 2018). Babies with neonatal abstinence syndrome (NAS) who breastfeed experience fewer and milder symptoms of opiate withdrawal, feed better, and are ready for discharge from the hospital sooner (Tsai & Doan, 2016; Wachman et al., 2016; Yonke, et al., 2019). Maternal breastfeeding benefits include promotion of maternal infant bonding, decreased frustration, and improved participation in recovery (Tsai & Doan, 2016; Wachman et al., 2016).

Purpose and Rationale

Increased breastfeeding education is recommended for women in MAR both during pregnancy and postpartum to improve rates of breastfeeding initiation (Demirci, Bogen & Kliensky, 2015; Graves, Turner, Nader, & Sinha, 2016; Hicks, Morse, & Wyant, 2018; Holmes, Schmidlen, & Kurzum, 2017; Ito, 2018; Reece-Stremtan, Marinelli, & ABM, 2015; MacVicar, Humphrey, & Forbes-McKay, 2017; Wu & Carre, 2018; Yonke et al., 2019). Breastfeeding education is associated with increased breastfeeding exclusivity at discharge (Yonke et al, 2019).

Education should be tailored to include both maternal and infant benefits of breastfeeding specific to this population. Yonke, et al. (2019) found that the maternal decision to breastfeed was impacted by explanation of benefits of breastfeeding especially by the potential to improve bonding, support of infant immune system, and promotion of infant growth and development. The need to terminate breastfeeding should the mother begin using illicit substances again must be made clear (Holmes, Schmidle, & Kurzum, 2017; Ito, 2018). Risks of using additional substances, including marijuana, should be explained. The mother should be educated that the rationale for not using substances is not a legal issue but how the substance is transferred to the

baby through the breastmilk (McLafferty et al., 2016). Additional education should focus on continued use of methadone or buprenorphine during the postpartum period, and explanation that breastfeeding is safe due to the minimal amount of either medication that is transferred through the breastmilk (Ito, 2018; Jansson et al., 2016).

Background/Significance

A Healthy People 2020 goal is to increase the overall proportion of infants who have ever breastfed to 81.9% (U.S. Department of Health & Human Services [HHS], 2019). Breastfeeding is recommended to improve maternal and neonatal outcomes (ACOG, 2017; Cleveland, 2016; Hicks, Morse, & Wyant, 2018; McLafferty et al., 2016; Reece-Stremtan, Marinelli, & ABM, 2015; Tsai & Doan, 2016). Women participating in MAR benefit from increased breastfeeding education that is tailored to their individual circumstance during pregnancy and during the postpartum period to improve rates of breastfeeding.

The CDC has a call to action for breastfeeding encouragement that promotes education regarding the importance of breastfeeding for women and their infants and teaching them how to breastfeed (HHS, 2011). The CDC also recommends that lactation consultants are available to patients and staff, and for nursing staff to be educated regarding the importance of breastfeeding and breastfeeding support. Lactation consultants and staff providing breastfeeding education should be encouraged to address any potential barriers to breastfeeding promptly to prevent interference with successful breastfeeding (McGlothen, Cleveland, & Gill, 2018).

Mothers in MAR are considered a special population and require education tailored to their specific needs (Hicks, Morse, & Wyant, 2018; Tsai & Doan, 2016). Family members and support people should be included in education regarding benefits of breastfeeding and MAR (Yonke et al., 2019). Neither methadone nor buprenorphine are present in significant amounts in

breastmilk (Ito, 2018; Wachman et al., 2016; Wu & Carre, 2018). Currently no breastfeeding education is being given at an inpatient perinatal MAR program. Evidence supports providing education to support maternal understanding and support maternal decisions to breastfeed in the future.

Internal Evidence

A large system-based hospital within the Phoenix Metropolitan area. The Agency currently has a program for initiation of MAR for OUD in pregnant patients of any gestational age. Patients check in through the hospital emergency room or Obstetrics (OB) Triage and ask for help. They are then admitted to the Antepartum Department (APU) in the hospital under the care of a maternal fetal medicine provider who initiates either methadone or buprenorphine. Routine prenatal labs appropriate for the trimester are collected. A complete OB ultrasound, and a maternal electrocardiogram (EKG) are also completed. During their stay the patients are provided with outpatient resources that will allow them to continue treatment throughout their pregnancy. They follow up with the maternal fetal medicine providers in the outpatient setting for prenatal care. Currently no breastfeeding education is offered to these women during their hospital stay.

In 2018 the Agency had a breastfeeding exclusivity rate of 51.4%, which is well below the recommended rate of 81.9%. Currently the data includes all mothers who breastfeed exclusively without considering other factors. Lactation consultants are available within the hospital seven days a week. There is no protocol for lactation consultants to meet with pregnant patients in the MAR program in the APU. Breastfeeding education in the Agency begins at birth for this population. There is a system-wide policy that does not allow for breastfeeding education

or support if a mother has used illicit or nonprescribed medications in the two months prior to delivery.

PICOT Question

This inquiry has led to the clinically relevant PICOT question, “In pregnant women initiating medication assisted recovery, either methadone or buprenorphine, in a hospital setting (P), can breastfeeding education (I) compared to the current practice of no education (C), improve maternal understanding of the benefits of breastfeeding and increase intention to breastfeed (O), during their hospital stay (T)?

Search Strategy

Three databases (CINAHL, PubMed, Cochrane) were searched in March 2019. Keywords for the search were combined with Boolean OR and each set of search terms was combined with Boolean AND to search across title, abstract, and keywords. Search terms included: breastfeeding, methadone, buprenorphine, opioid agonist therapy, opioid use disorder, perinatal, education, support, lactation, breastmilk, skin to skin, and benefits. The reference lists of existing reviews and eligible studies were reviewed after an exhaustive search of databases to ensure capture of all relevant studies. Limits were English articles from 2014 through 2019. The initial search yielded 6,420 articles. Articles met criteria for inclusion if they were of moderate to high quality, qualitative or quantitative, or brought additional support to the PICOT question. Twenty-six articles were selected for inclusion. (Appendix A).

Critical Appraisal and Analysis

Ten studies were retained for this review (Appendix B). Studies were retained if the study population included pregnant or breastfeeding women participating in MAR, included a discussion of at least one breastfeeding outcome, or breastfeeding education. Reviewed studies

included one cohort study, one cross sectional analysis, one randomized controlled trial, two meta-analyses, two reviews, and three retrospective cohort studies. Quality and strength of the evidence was determined by Fineout-Overholt and Melnyk's (2015) rapid critical appraisal process. Most studies included women with OUD, women in MAR, safety and efficacy of breastfeeding with MAR, breastfeeding initiation, or breastfeeding education. The exceptions were the study by Peisch et al. (2018) which focused on parents with OUD. There was limited bias in the included articles. Demographic data included in the studies was moderately described. All studies included primarily female who were pregnant or postpartum, and their infants. The exceptions were the study by Peisch et al. (2018) that included parents but did not specify age ranges. The majority of studies were conducted in the United States.

Measurement tools varied depending on the type of study. Measurement tools included review of literature, review of databases, review of patient electronic health records (EHR), telephone interviews, and measurement via mass spectrometry. Primary outcomes of interest focused on impact of OUD on systems, breastfeeding in women participating in MAR, barriers to breastfeeding, safety and efficacy of breastfeeding in women participating in MAR, breastfeeding education, and maternal perceptions of breastfeeding during MAR. Most studies reported confidence intervals, means, standard deviations, effect sizes, and level of significance.

Synthesis of Evidence

The evidence suggests that initiation of breastfeeding education can positively impact breastfeeding intention for women in MAR. This population has a low rate of breastfeeding intention, initiation and exclusivity when compared to the general population. Barriers to breastfeeding are suggested to be the result of maternal, infant, societal, or socioeconomic factors. There is often a lack of education related to the safety and benefit of breastfeeding while

participating in MAR. Healthcare providers are positioned to provide individualized and nonjudgmental breastfeeding education to women participating in MAR. However, provider prejudice and lack of support can negatively impact breastfeeding intention. Institutional policies that increase maternal infant separation have been negatively correlated to breastfeeding success.

Rubin (1976) identified the second trimester as a time when the pregnancy has now become real. During this trimester there is an increase in receptiveness to education and ideas promoting a safe environment for the pregnancy and the baby. Women in the second trimester have begun to feel the baby move, and this develops an increased awareness of the baby as a life growing within her. This awareness helps to develop bonding, encourage maternal learning and tasks. During this time women begin to look for acceptance of their pregnancy from their family and peer group.

Education should clearly outline the benefits of breastfeeding to the mother and the infant. A simple explanation supporting continued participation of MAR, and reassurance that breastmilk contains a minimal amount of the medication in comparison to maternal dose should be included. The topic of termination of breastfeeding if she continues or resumes use of illicit substances should be discussed. In an in-patient healthcare setting, initiation of breastfeeding education as pregnant women initiate MAR could help to improve understanding of maternal and neonatal benefits of breastfeeding initiation and exclusivity which can lead to improved intention to exclusively breastfeed.

Theory Application/Conceptual Framework

The Quality Health Outcomes Model (QHOM) was selected as the conceptual framework for this project due to its ease of application to system level interventions (Mitchell, Ferketich, & Jennings, 1998). (Appendix C). The QHOM uses a broad linear approach to evaluate

relationships between structural and process variables to outcomes. Characteristics of the system and clients impact intervention outcomes. The QHOM has been used to evaluate system and participant characteristics at the site of interventions and to examine the impact of multiple variables on the intervention outcome. Multiple variables were identified that impacted project initiation and outcomes.

EBP Model/Quality Improvement Model

The Knowledge to Action (KTA) Framework was chosen as the quality improvement model for this project. (Appendix D). The purpose of the KTA is to guide identification of gaps between research (knowledge) and practice and to guide application of knowledge to improve health outcomes (Graham et al., 2006). KTA was applied to this project because the project goal was to apply knowledge of breastfeeding benefits during MAR to influence a practice change. The desired practice change is the inclusion of a lactation consultation into the MAR program. KTA was indirectly applied when appraising studies relevant to the intervention. KTA helped to guide development of clear, concise education on recommendations to staff impacted by the intervention. Identification of barriers that may impact application of knowledge is helpful when examining whether the intervention will result in a sustainable change in practice.

Methods/Results

The project was presented to department leaders when the need was identified. Once department leadership agreed with the project it could move forward in the Agency approval process. The initial project was presented in August of 2019 to the Agency Professional Practice Committee. It included a lactation consult for all pregnant women beginning MAR utilizing either methadone or buprenorphine. Following several revisions, the final plan for the project focused on a lactation consult for women in their 2nd trimester.

The final plan for the project aligned with evidence that the 2nd trimester is the time when learning related to the maternal role is most accepted (Rubin, 1976). Additionally, this aligns with Agency policies regarding breastfeeding support. Following approval in October 2019 by the Agency Professional Practice Committee, approval as an exempt project was obtained from the ASU IRB in November 2019. Following notification to the Agency of the ASU IRB approval, notification that a second level of approval was needed from the Agency Research Determination Committee which is in place to ensure that research done at the Agency facilities does not violate Health Insurance Portability and Accountability Act (HIPPA) regulations for patients. This final level of approval was obtained in early December of 2019.

The project was implemented on December 17, 2019. Implementation began with education of Antepartum staff and lactation consultants on background and significance, current evidence supporting breastfeeding and breastfeeding education during MAR, and the process of evaluation. During the time that the process was evaluated, there were 4 patients in the second trimester admitted to the APU department for MAR. Three did not meet criteria for inclusion, resulting in one patient receiving the lactation consult. Given the small N of one for the project, evaluation of outcomes resulted in a change of focus to an evaluation of the process of implementation of a change in practice within a department.

Discussion

The available evidence regarding the topic of women in recovery for OUD links breastfeeding to maternal and neonatal benefits. Breastfeeding education should be initiated early and continued throughout the pregnancy and postpartum period. Education should be non-judgmental and specific to the patient's situation. Inclusion of breastfeeding education for

pregnant women beginning MAR can help them to focus on their recovery and increase their intention to breastfeed exclusively.

There were significant barriers to the implementation of this project. During the approval process there was a change in leadership both within the department and within the system. Multiple rewrites of the initial project proposal added a significant amount of time to prepare the project and gain approval from the ASU IRB. The layered approval required at the facility was not a dynamic, well communicated process and further delayed project initiation. There was a lack of support from department leadership once the project was implemented to facilitate participant identification and implementation of the lactation consult.

Project limitations included time constraints and a low participation rate. It is unknown whether more time would have resulted in increased participation. The bedside nurses in the APU and the lactation consultants were all receptive to the education. Following project implementation, the key drivers of the project were the APU nurses. They facilitated identification of potential participants, communicated regarding any issues or questions, and ordered the lactation consult appropriately. The single participant verbalized the importance of the lactation consult to the MAR program. While the inclusion of a lactation consult during the initiation of MAR is important to long term outcomes, it is unknown whether it will continue following project termination.

Recommendations for system policy changes that will support breastfeeding in mothers in MAR include continued lactation education during the antenatal period when patients enrolled in MAR are identified, regardless of reason for admission. Mothers involved in MAR should be offered the same support as all breastfeeding mothers including skin to skin, and early initiation of breastfeeding. System policy that routinely separates mothers and babies being evaluated for

NAS should be updated to decrease instances of separation of mother baby units and make this the exception. Staff education regarding benefits of breastfeeding support to mothers in MAR and their babies should continue to support best outcomes.

Recommendations for future projects include additional evaluation of the impact of antenatal breastfeeding education on intention or initiation of breastfeeding, and qualitative studies of attitudes towards breastfeeding during MAR. Evaluation of rooming in for breastfeeding mothers in MAR will support system changes.

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Appendix A:

Evaluation Table

Citation	Theory/Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Major variables studied and Their Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	Level of Evidence/Decision for Use/Application to Practice
<p>Clemans-Cope, et al. (2019). Pregnant women with opioid use disorder & their infants in three state Medicaid programs in 2013-2016</p> <p>Country: U.S.</p> <p>Funding: Center for Medicare & Medicaid Innovation</p> <p>Bias: Selection bias (3 states, Medicaid enrolled)</p>	NS (Transitional Care Model)	<p>Design: Retrospective Cohort</p> <p>Purpose: To “analyze maternal & infant Medicaid claims data and infant birth records in three states for the year before and after a birth, in 2014 or 2015, examining health, health care use, treatment & neonatal outcomes.”</p>	<p>N= 37,782 (2014) N= 34,304 (2015)</p> <p>Demographics: Women, gave birth in 2014 or 2015, Medicaid-enrolled,</p> <p>Setting: NS, included mix of urban & rural counties, 1 northwestern state, 1 southwestern state, 1 southern state</p> <p>Inclusion: mother-infant dyads, full benefit Medicaid for 1 mo. Before</p>	<p>IV1: OUD IV2: other SUD IV3: no SUD</p> <p>DV: Medicaid enrolled delivered live infant</p> <p>Time Frame of the Intervention: 2013-2016, depending on date of del.</p>	Search of Medicaid claims, eligibility records, & birth certificates	SAS 9.3 & STATA 15, regression analysis & linear combination	<p><i>p</i> value – 0.05</p> <p>IV1: 2.2% of total 52.1% psych 22.7% treatment rate, del.- \$22,485 - \$34, 885</p> <p>IV2: 5.9% of total 46.2% psych 7.9% treatment rate, Del.-\$16,171</p> <p>IV3: 91.9% of total 9.6% psych Del.- \$11,196</p>	<p>LOE: III</p> <p>Strengths: Large sample size, 3-year time frame</p> <p>Weaknesses: Limited to Medicaid patients with full benefits, limited to 3 states, data limited by documentation in record</p> <p>Conclusions: Higher costs of delivery & health care noted with SUD, especially OUD; low numbers of treatment during pregnancy and PP</p> <p>Feasibility: High, retrospective review lack of</p>

BF- Breastfeeding, BW- Birth weight, CG- control group, CI- Confidence interval, del.- delivery, DV- Dependent variable, ed.-education, EMR- electronic medical record, GA- Gestational age, IG- Intervention group, IV-Independent variable, LOE- level of evidence, M- mean, mo.- month, N- -sample size (population), n- sample size (studies), N/A- Not applicable, NAS- Neonatal Abstinence Syndrome, NIDA- National Institute on Drug Abuse, NIH – National Institute of Health, NIS- National Inpatient Sample, NS- Not stated, OMT- Opioid maintenance Treatment, OUD- Opioid use disorder, PP- Postpartum, PRC- Pregnancy Recovery Center, Psych- Psychiatric, REACH- Racial and Ethnic Approaches to Community Health, RCT- Randomized Controlled Trial, SAS- Statistical software program, SE- Socioeconomic status, STRATA- Statistical software program, SUD- Substance use disorder, U.S.-United States, w/- with, w/o- without, yrs.- years, Z- standard deviation from mean, & - and

			delivery &/or 11 months PP, with valid BW & GA Exclusion: Not on full Medicaid benefits during specified time frame, no listed BW or GA. Attrition: N/A					attrition, data limited to included claims and documentation.
Citation	Theory/Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Major variables studied and Their Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	Level of Evidence/Decision for Use/Application to Practice
Hatzis et al., (2017). Quality of caregiving in mothers with illicit substance use: A systematic review & meta-analysis Country: Australia Funding: Griffith University Postgraduate Research Scholarship	NS (Maternal Role Attainment Theory)	Design: Meta-Analysis & Comprehensive Systematic review Purpose: To “assess the extent to which mothers with substance misuse have compromised caregiving.”	N=3433 mother-infant dyads n= 24 Demographics: Setting: Inclusion: English language, range 1995-2015; Mothers of children aged birth – 3 yrs, w/ current SUD &/or on opioid replacement therapy d/t hx of OUD, &/or	IV1: Mothers using illicit substances or in treatment IV2: Mothers not using illicit substances or in treatment DV1: maternal sensitivity DV2: child responsiveness Timeframe of the Intervention: N/A	Database search for articles based on search terms	Random effects model	DV1: Population effect size: 0.46 CI: 0.31-0.61 Z= 5.99 <i>p</i> <.00001 (higher in non-substance abusing) DV2: Population effect size 0.32 (95% CI: 0.06-0.59, Z= 2.37 <i>p</i> =.02) (higher in non-substance using mothers)	LOE: I Strengths: Large sample from included studies Weaknesses: high heterogeneity (DV1: 69%, DV2: 77%) Possibly d/t SE status, Education, design, study inclusion. Conclusions: Synthesis of literature including mothers with SUD & quality of caregiving

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<p>Bias: Selection bias</p>			<p>in residential treatment d/t SUD, comparison of non-SUD mothers included, w/ observed interactions</p> <p>Exclusion: non-English language, outside range of dates, duplicate studies, primary focus not caregiving, ineligible population, no matched comparison group, maternal sensitivity or child responsiveness not measured</p> <p>Attrition: N/A</p>					<p>demonstrated higher quality in mother's w/o SUD.</p> <p>Feasibility: High, retrospective review of studies lack of attrition, limited by available studies meeting inclusion criteria.</p>
Citation	Theory/Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Major variables studied and Their Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	Level of Evidence/Decision for Use/Application to Practice
<p>Jansson, et al. (2016). Maternal Buprenorphine Maintenance & Lactation.</p>	<p>NS (Pender's Health Promotion Model)</p>	<p>Design: Cohort Study</p> <p>Purpose: To determine concentrations of</p>	<p>N=10 buprenorphine-maintained females, & N=9</p>	<p>IV: Breastmilk & plasma samples at</p> <p>DV: Amount of</p>	<p>Analysis of breastmilk & plasma by liquid chromatography tandem mass spectrometry</p>	<p>Spearman correlation</p>	<p>Day 2 0.85 (.002) Day 30 0.76 (.030) (maternal dose/plasma)</p>	<p>LOE: IV</p> <p>Strengths: consistent sample</p>

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<p>Country: U.S.</p> <p>Funding: NIH/NIDA supplement</p> <p>Bias: Selection bias</p>		<p>buprenorphine and its active metabolites in human milk, maternal plasma, infant plasma in buprenorphine-maintained women & their infants.”</p>	<p>infants</p> <p>Demographics: (maternal) M age- 26.1 yrs M ed. level- 12.2 yrs M GA to begin treatment- 17.3</p> <p>Setting: Large medical center in Baltimore, MD</p> <p>Inclusion: opioid dependent, buprenorphine-maintained women wanting to breastfeed w/ no restrictions</p> <p>Exclusion: preterm delivery, medical complications, positive urine toxicology indicating recent use of illicit substances</p> <p>Attrition: (Maternal) Day 2 & 3- 0%, Day 4 & 14- 10%, Day 30 – 20%,</p>	<p>buprenorphine & active metabolites</p> <p>Timeframe of the Intervention: Day 2, 3, 4, 14 & 30 post birth.</p>			<p>Day 2 0.86 (.002) Day 30 0.76 (.049) (maternal dose & breastmilk concentration)</p>	<p>Weaknesses: small sample size, attrition rate 20% by day 30 (N=2)</p> <p>Conclusions: Supports recommendations for breastfeeding in this population. Further studies are needed in exclusively breastfeeding mothers with larger sample size.</p> <p>Feasibility: Moderate, requires resources for lab analysis, increased chances of attrition d/t length of study timeframe.</p>
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			(Infants) Day 14 – 0%					
Citation	Theory/Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Major variables studied and Their Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	Level of Evidence/Decision for Use/Application to Practice
Krans, et al. (2018). The Pregnancy Recovery Center: A women-centered treatment program for pregnant & postpartum women with opioid use disorder. Country: U.S. Funding: Partially supported by NIDA Bias: Selection bias	NS (Pender’s Health Promotion Model)	Design: Retrospective cohort Purpose: “To evaluate the impact of women-centered substance abuse treatment programming on outcomes among pregnant women with OUD.”	N= 248 IG: 71 CG: 177 Demographics: Female IG M age- 28.9 BF during del. hospitalization: 39 BF at discharge: 34 CG M age- 28.7 BF during del. hospitalization: 96 BF at discharge: 70 Setting: Delivery occurred at University Associated Medical Center between July 2014- July 2016.	IV1: in PRC IV2: not at PRC DV1: pregnant women DV2: on buprenorphine Timeframe of the Intervention: July 2014 – July 2016	EMR review	Chi-square & t test conducted with STATA 15.	buprenorphine dose- IG: 16.0mg CG: 14.1 mg (p=0.02) Attendance to PP visit IG: 67.9% CG: 52.6% (p=0.05) Rate of BF decrease IG: -14.7% CG: - 37.1%	LOE: III Strengths: Large sample size, comparison samples homogenous. Weaknesses: IG & CG sample size not balanced, performed at single center in large metropolitan center, primarily Caucasian (95.7-96.5%) Conclusions: Findings indicate improved outcomes and compliance to care with a women-centered treatment facility. Supports need for BF education to improve BF rates. Feasibility: Moderate, would require a women’s

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			<p>Inclusion: Pregnant female, OUD, participants in PRC or non-PRC treatment services, buprenorphine maintained,</p> <p>Exclusion: missing prenatal & delivery information, methadone maintained</p> <p>Attrition: N/A Retrospective review</p>					centered treatment facility to be compared to non-women’s centered treatment facility for comparison of results for application to practice.
Citation	Theory/Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Major variables studied and Their Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	Level of Evidence/Decision for Use/Application to Practice
Peisch, et al. (2018). Parental opioid abuse: A review of outcomes, parenting, & parenting interventions. Country: U.S. Funding: University of	NS (Modeling & Role Modeling Theory)	Design: Meta-Analysis of RCTs Purpose: “review rigorously conducted studies examining the association of opioid abuse with parenting & child outcomes & to review parenting intervention	n=21 Demographics: Parents with SUD, primarily OUD Setting: varied Inclusion: English language studies with comparison	IV1: child outcomes IV2: Parenting behaviors DV: Parents w/ OUD Timeframe of the Intervention:	Review of available studies from databases with associated terms	Inferential statistical analysis	IV1: decreased social support may impact decreased social, academic functioning IV2: studies reviewed did not favor positive or negative	LOE: I Strengths: Studies were across large timeframe, Weaknesses: Limited sample size of studies that met inclusion criteria, studies did not all match in demographic or intervention data.

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<p>Vermont REACH Grant, the College of Arts & Sciences, the College of Education & Social Sciences.</p> <p>Bias: Selection bias.</p>		<p>programs with these caregivers.”</p>	<p>group, quantitative data w/ inferential statistical analyses.</p> <p>Exclusion: Non-English language studies, at least 49% of parents in study did not have OUD.</p> <p>Attrition: N/A</p>	<p>Studies from 1986-2015 reviewed</p>			<p>behaviors in parents with OUD</p>	<p>Conclusions: Indicates need for further study on the topic. Suggestive of need to support parenting skills in parents with OUD.</p> <p>Feasibility: High, retrospective review of studies can be repeated to be applied to practice.</p>
Citation	Theory/Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Major variables studied and Their Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	Level of Evidence/Decision for Use/Application to Practice
<p>Tsai & Doan. (2016). Breastfeeding among mothers on opioid maintenance treatment: A literature review.</p> <p>Country: U.S.</p> <p>Funding: None stated</p>	<p>NS (Maternal Role Attainment Theory)</p>	<p>Design: Review of case-control studies</p> <p>Purpose: “Review of experimental/quasi-experimental studies over last 10 years that examine interventions aimed at increasing rates of breastfeeding initiation and duration in mothers receiving OMT.</p>	<p>n=9</p> <p>Demographics: Female, pregnant or PP, receiving OMT.</p> <p>Setting: varied, primarily inpatient</p> <p>Inclusion: English language, human studies, from January</p>	<p>IV1: BF initiation IV2: BF duration DV: Mothers on OMT</p> <p>Timeframe of the Intervention: varied</p>	<p>Review of studies meeting inclusion criteria</p>	<p>NS</p>	<p>IV1 highest in rooming in (62.5%)</p> <p>Intervention groups had higher rates of IV1 & IV2, than no intervention</p>	<p>LOE: III</p> <p>Strengths: Cohesive population</p> <p>Weaknesses: Limited number of studies,</p> <p>Conclusions: Indicates need for additional BF support to improve BF rates in this population.</p>

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<p>Bias: Selection bias.</p>			<p>2005- October 2015, preference to experimental & quasi-experimental studies.</p> <p>Exclusion: Non-English language, studies w/o original data</p> <p>Attrition: N/A</p>					<p>Feasibility: High, Supports need for patient education & support to improve BF rates, applicable to practice.</p>
Citation	Theory/Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Major variables studied and Their Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	Level of Evidence/Decision for Use/Application to Practice
<p>Whiteman, et al. (2014). Maternal opioid drug use during pregnancy & its impact on perinatal morbidity, mortality, & the costs of medical care in the U.S.</p> <p>Country: U.S.</p> <p>Funding: Not stated, reviewed by IRB of</p>	<p>NS (Transitional Care Model)</p>	<p>Design: Cross Sectional Analysis</p> <p>Purpose: “To identify factors associated with opioid use during pregnancy & to compare perinatal morbidity, mortality & healthcare costs between opioid users & non-users.”</p>	<p>N= 55,781,965 Pregnancy related hospitalizations N=138,224 associated with opioid use</p> <p>Demographics: Pregnancy related discharges between 1998-2009.</p> <p>Setting: Inpatient</p> <p>Inclusion: NIS database,</p>	<p>IV1: opioid use IV2: no opioid use</p> <p>DV1: pregnancy DV2: cost of health care costs</p> <p>Timeframe of the Intervention: data between 1998-2008</p>	<p>Review of pregnancy related hospital discharges from 1998-2009 using NIS.</p>	<p>Two sided statistical tests with level of significance at 5%.</p>	<p>Increased rates of use of opioids in pregnancy as study progressed.</p> <p>Primary payor-Private #1, Medicaid #2</p>	<p>LOE: III</p> <p>Strengths: large sample size, length of study.</p> <p>Weaknesses: Opioid use not identified during hospital stay was missed, deidentified information did not allow for association of mother-infant dyads or allow for identification of multiple hospitalization</p>

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<p>University of South Florida</p> <p>Bias: Selection bias.</p>			<p>pregnancy related discharges</p> <p>Exclusion: Not pregnancy related</p> <p>Attrition: N/A</p>					<p>during the specified time frame.</p> <p>Conclusions: Study indicated increased rates of maternal co-morbidities, longer hospital stays, increased mortality, poor fetal growth & survival associated with opioid use in pregnancy.</p> <p>Feasibility: Moderate, applicable to practice as background for increased costs associated with opioid use in pregnancy.</p>
Citation	Theory/Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Major variables studied and Their Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	Level of Evidence/Decision for Use/Application to Practice
<p>Wong et al. (2014). Antenatal education to increase exclusive breastfeeding:</p>	<p>NS (Pender’s Health Promotion Model)</p>	<p>Design: RCT</p> <p>Purpose: “evaluate the effectiveness of a professional one-to-one antenatal breastfeeding</p>	<p>N= 469 IG-233 CG-236</p> <p>Demographics: Pregnant females</p>	<p>IV: Exclusive breastfeeding rates</p> <p>DV1: Standard antenatal care</p>	<p>Telephone interviews</p>	<p>Kaplan-Meier Survival curves & unadjusted Cox proportional</p>	<p>Intervention group no more likely to continue exclusive breastfeeding, at 6 weeks</p>	<p>LOE: I</p> <p>Strengths: Adequate sample size, minimal rate of attrition</p>

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<p>A randomized controlled trial.</p> <p>Country: Hong Kong</p> <p>Funding: Grant from the University of Hong Kong.</p> <p>Bias: Selection bias.</p>		<p>support and education intervention on the exclusivity & duration of breastfeeding.”</p>	<p>Setting: 2 public antenatal clinics in Hong Kong</p> <p>Inclusion: at least 18 yrs., Cantonese speaking, primiparous, 35 weeks GA or greater, singleton pregnancy, no complications, intends to BF, plans to stay in Hong Kong for at least 6 mo. PP.</p> <p>Exclusion: Not entitled to health benefits in Hong Kong &/or not a Hong Kong resident</p> <p>Attrition: IG:6.4% CG: 4.7%</p>	<p>DV2: 1-1 breastfeeding support & education session</p> <p>Timeframe for the Intervention: 6 weeks, 3 months, & 6 months PP.</p>		<p>hazards regression</p>	<p>(37.8% vs. 36.4%, $P=.77$, 95% CI), at 3 months (26.6% vs. 25.9%, $P=.85$, 95% CI)</p> <p>93.6% -95.3% rate of completion</p>	<p>Weaknesses: Study population limited, may not apply to other cultures or geographical areas.</p> <p>Conclusions: A single one on one antenatal education and support session did not significantly impact BF rates.</p> <p>Feasibility: Moderate, further education is needed to increase BF initiation and duration rates with consideration to barriers. Applicable to practice as rationale for individualized education.</p>
Citation	Theory/Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Major variables studied and Their Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	Level of Evidence/Decision for Use/Application to Practice
<p>Wu & Carre. (2018). The impact of breastfeeding</p>	<p>NS (Pender’s Health Promotion Model)</p>	<p>Design: Review of experimental/quasi-</p>	<p>n= 7</p> <p>Demographics:</p>	<p>IV1: breastfed infants IV2: formula fed infants</p>	<p>Review of studies from databases with associated search terms</p>	<p>NS (varied)</p>	<p>BF associated with decreased length of</p>	<p>LOE: III</p>

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<p>on health outcomes for infants diagnosed with neonatal abstinence syndrome: A review.</p> <p>Country: U.S.</p> <p>Funding: Not stated.</p> <p>Bias: Selection bias, & both authors work for University of Central Florida.</p>		<p>experimental studies</p> <p>Purpose: Evaluation of literature that suggests breastfeeding may have the potential to reduce symptom severity & improve outcomes of infants with NAS</p>	<p>Women on OMT, infants w/ NAS</p> <p>Setting: varied</p> <p>Inclusion: human studies, English language, from 1997-2018, women with SUD receiving OMT, & infants with NAS</p> <p>Exclusion: non-English language studies</p> <p>Attrition: N/A</p>	<p>DV1: Postpartum women on MAT DV2: Infants diagnosed with NAS</p> <p>Timeframe of the Intervention: Varied, studies included from 1997-2018</p>			<p>hospital stay in infants with NAS.</p> <p>BF associated w/ decreased symptoms of NAS with BF.</p>	<p>Strengths: Studies supportive of BF in OMT.</p> <p>Weaknesses: Small sample of studies.</p> <p>Conclusions: BF improves maternal & infant outcomes in women receiving OMT. Overall percentage of this population BF remains small, supports need for additional information.</p> <p>Feasibility: High, rates of success and improved outcomes supports use in practice.</p>
Citation	Theory/Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Major variables studied and Their Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	Level of Evidence/Decision for Use/Application to Practice
<p>Yonke et al., (2019). Breastfeeding intention compared with breastfeeding postpartum among women receiving medication-</p>	<p>NS (Pender's Health Promotion Model or Maternal role attainment theory)</p>	<p>Design: Retrospective cohort study</p> <p>Purpose: "To determine difference between stated intention to breastfeed prenatally in</p>	<p>N= 228 women/infant dyads</p> <p>DV1-107 DV2-121</p> <p>Demographics: Women, pregnant,</p>	<p>IV1: Intention to breastfeed</p> <p>IV2: breastfeeding rates post delivery</p> <p>DV1: methadone use</p>	<p>EMR review</p>	<p>Chi-square tests</p>	<p>84% intended to breastfeed</p> <p>DV1: initiated 71%, 21% exclusive BF at dc, 12% exclusive BF at 2-month PP visit</p>	<p>LOE: IV</p> <p>Strengths: Adequate sample size, consistent sample</p>

BF- Breastfeeding, **BW-** Birth weight, **CG-** control group, **CI-** Confidence interval, **del-** delivery, **DV-** Dependent variable, **ed-** education, **EMR-** electronic medical record, **GA-** Gestational age, **IG-** Intervention group, **IV-**Independent variable, **LOE-** level of evidence, **M-** mean, **mo.-** month, **N-** -sample size (population), **n-** sample size (studies), **N/A-** Not applicable, **NAS-** Neonatal Abstinence Syndrome, **NIDA-** National Institute on Drug Abuse, **NIH-** National Institute of Health, **NIS-** National Inpatient Sample, **NS-** Not stated, **OMT-** Opioid maintenance Treatment, **OOD-** Opioid use disorder, **PP-** Postpartum, **PRC-** Pregnancy Recovery Center, **Psych-** Psychiatric, **REACH-** Racial and Ethnic Approaches to Community Health, **RCT-** Randomized Controlled Trial, **SAS-** Statistical software program, **SE-** Socioeconomic status, **STRATA-** Statistical software program, **SUD-** Substance use disorder, **U.S.-**United States, **w/-** with, **w/o-** without, **yrs.-** years, **Z-** standard deviation from mean, **& -** and

<p>assisted treatment.</p> <p>Country: U.S.</p> <p>Funding: part of a larger study, no financial support reported.</p> <p>Bias: Authors work with patients at the clinic where study occurred & selection bias.</p>		<p>women taking methadone or buprenorphine compared with breastfeeding at discharge & 2 months postpartum. Secondary outcome to determine if breastfeeding was more common in women taking buprenorphine.”</p>	<p>enrolled in perinatal substance abuse program affiliated with university</p> <p>Setting: a university affiliated prenatal care program</p> <p>Inclusion: Began OMT with methadone or buprenorphine prior to 36 weeks GA, plan to BF, delivered between June 2011 & June 2015 at 36 weeks GA or greater, at least 3 prenatal visits with university prenatal care program.</p> <p>Exclusion: Illicit drug use at time of del., twin gestation, did not keep 2 month PP visit.</p> <p>Attrition: N/A. Retrospective study.</p>	<p>DV2: buprenorphine use</p> <p>Timeframe of Intervention: June 2011- June 2015</p>			<p>DV2: initiated 82.6%, 31.4% exclusive BF at dc, 8.9% exclusive BF at 2-month PP visit</p>	<p>Weaknesses: unable to determine what impacted decision to BF</p> <p>Conclusions: Results indicated a low incidence of breastfeeding initiation and duration despite stated BF intentions. Prevalence of BF was higher in buprenorphine group. Study suggests need for additional education regarding benefits of BF to this population.</p> <p>Feasibility: High, Follow up can be performed during hospitalization for delivery & during PP visit. Applicable to practice, need for education regarding BF benefit.</p>
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BF- Breastfeeding, BW- Birth weight, CG- control group, CI- Confidence interval, del.- delivery, DV- Dependent variable, ed. -education, EMR- electronic medical record, GA- Gestational age, IG- Intervention group, IV-Independent variable, LOE- level of evidence, M- mean, mo.- month, N- -sample size (population), n- sample size (studies), N/A- Not applicable, NAS- Neonatal Abstinence Syndrome, NIDA- National Institute on Drug Abuse, NIH – National Institute of Health, NIS- National Inpatient Sample, NS- Not stated, OMT- Opioid maintenance Treatment, OUD- Opioid use disorder, PP- Postpartum, PRC- Pregnancy Recovery Center, Psych- Psychiatric, REACH- Racial and Ethnic Approaches to Community Health, RCT- Randomized Controlled Trial, SAS- Statistical software program, SE- Socioeconomic status, STRATA- Statistical software program, SUD- Substance use disorder, U.S.-United States, w/- with, w/o- without, yrs.- years, Z- standard deviation from mean, & - and

Appendix B:
Synthesis Table

Studies		Clemons-Cope	Hatzis	Jansson	Krans	Peisch	Tsai	Whiteman	Wong	Wu	Yonke
Basics	Year	2019	2017	2016	2018	2018	2016	2014	2014	2018	2019
	LOE	III	I	IV	III	I	III	III	I	III	IV
	Design	RC	MA	CS	RC	MA	REV	CSA	RCT	REV	RC
	Participants	72,086	3,433	10	248	21	9	138,224	469	7	228
Evaluations	M- OUD	X	X	X	X	X	X	X		X	X
	M- No OUD	X	X					X	X		
	Infants	X	X	X		X		X		X	
	BUP			X	X		X			X	X
	MTD						X			X	X
	BF Edu								X		
	TF				X						X
	OP				X						
Outcomes	MS		X			X					
	CS		X			X					
	BF in hosp			X	X		X		X	X	X
	BF at DC			X	X		X		X	X	X
	BF INT				X		X		X		X
	BF rates				X		X		X	X	X
	FF				X				X	X	X
	NAS									X	
	Cost to HCS	X						X			
	Breastmilk			X							

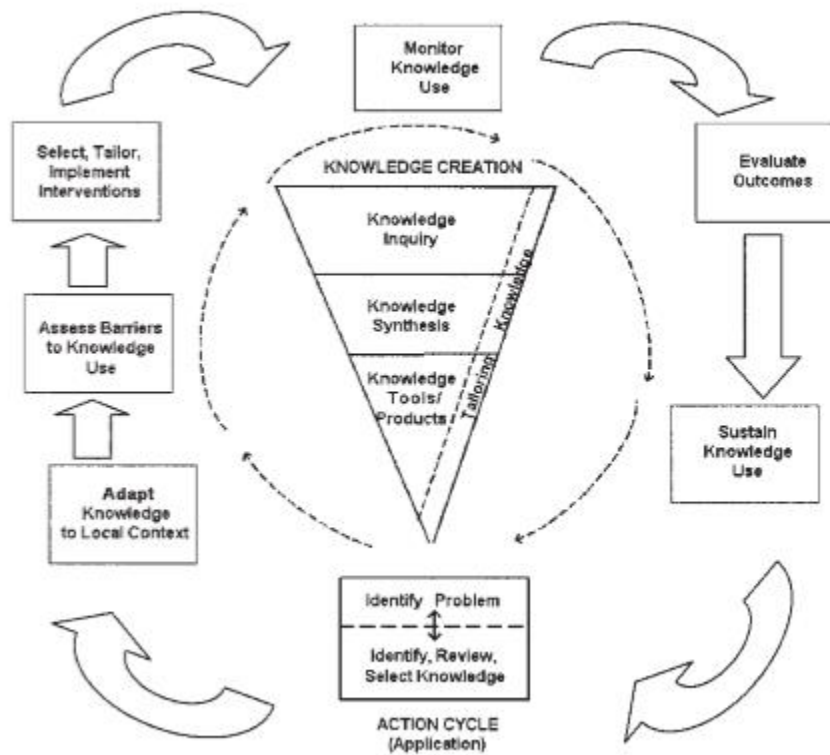
KEY: BF- breastfeeding, BUP- buprenorphine, CS- study, CSA- cross sectional analysis, CS- child sensitivity, DC- discharge, Edu- education, FF- formula fed, hosp-hospital, INT- intention, HCS- healthcare system, MA- meta-analysis, MS- maternal sensitivity, M-OUD-maternal opioid use disorder, M-no OUD- maternal no opioid use disorder, MTD- methadone, NAS- neonatal abstinence syndrome, OP- outpatient treatment, RC- retrospective cohort study, RCT- randomized controlled trial, REV- Review of studies, TF- treatment facility

Appendix C
Quality Health Outcomes Model



(Mitchell, Ferketich, & Jennings, 1998)

Appendix D Knowledge to Action Framework



(Graham et al., 2006)