THE INFLUENCE OF REGULAR BREAST MILK PUMPNG IN THE EARLY POSTPARTUM PERIOD ON BREASTFEEDING DURATION AND ACHIEVEMENT OF BREASTFEEDING INTENTION AMONG WOMEN IN THE U.S.

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A dissertation submitted to the faculty at the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the Department of Epidemiology in the Gillings School of Global Public Health.

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ABSTRACT

Jennifer Mary Yourkavitch: The influence of regular breast milk pumping in the early postpartum period on breastfeeding duration and achievement of breastfeeding intention among women in the U.S.
(Under the direction of Whitney Robinson)

Most mothers do not breastfeed in accordance with health recommendations. Returning to work can be a barrier to breastfeeding due to mother-infant separation. Expressing breast milk (pumping) is a way for mothers to continue breastfeeding when separated from their infants, but it is not known if regular pumping influences breast milk feeding duration and achievement of breastfeeding intentions. I estimated effects of regular pumping compared to non-regular/not pumping (noted as "non-regular") reported at month 2 on time to breast milk feeding (BMF) cessation (to 12 months) and time to exclusive BMF cessation (to six months), as well as achievement of breastfeeding and exclusive breastfeeding intentions, overall and for working and non-working women. I imputed missing data with 100 replications and used statistical weights to control for confounding and to address selection bias from the study design and drop-outs.

Overall, regular pumpers were more likely to stop BMF and exclusive BMF (weighted hazard ratio (wHR) 1.62; 95% confidence interval (CI) 1.47 – 1.78 for BMF and wHR 1.14; 95% CI 1.03 – 1.25 for exclusive BMF), and less likely to meet their breastfeeding intentions than non-regular pumpers (weighted risk ratio (wRR) 0.79; 95% CI 0.67 – 0.94). I observed no difference in achievement of exclusive BMF intention (wRR 1.05; 95% CI 0.84 – 1.31).

Among working women, I observed no effect of regular pumping compared to non-regular pumping, in terms of time to BMF cessation (wHR 0.90; 95% CI 0.75 – 1.07), exclusive BMF cessation (wHR 1.15; 95% CI 0.96 – 1.37), or achievement of breastfeeding intention (wRR 1.08; 95% CI 0.81 – 1.43) or exclusive breastfeeding intention (wRR 1.36; 95% CI 0.95 – 1.95). Among non-working women, regular pumpers had an increased hazard of BMF cessation (wHR 2.05; 95% CI 1.84 – 2.28), but not of exclusive BMF cessation (wHR 1.10; 95% CI 0.98 – 1.22), compared to non-regular pumpers. Regular pumpers were less likely to meet breastfeeding intentions (wRR 0.69; 95% CI 0.56 – 0.85), but had no difference in risk of not meeting exclusive breastfeeding intentions (wRR 0.70; 95% CI 0.69 – 1.22), than non-regular pumpers.

Regular pumpers may need specialized support to maintain BMF and to achieve their intentions.

To Robert Carty, my best friend, who loves and supports me unconditionally, which is the greatest gift.

In memory of Miriam Labbok, whose passion for breastfeeding inspired me and many others.

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PREFACE

The Results chapter of this dissertation contains two manuscripts, and the abstract contains summary text, which have been or will be submitted to journals for publication. Authorship for the first paper, "Early, regular breast milk pumping may lead to early breast milk feeding cessation," is Yourkavitch J, Rasmussen KM, Pence BW, Aiello A, Ennett S, Bengtson AM, Chetwynd E, and Robinson W. Authorship for the second paper, "Estimated effects of breast milk pumping on achievement of breastfeeding intentions in a sample of women in the U.S.," is Yourkavitch J, Ennett S, Rasmussen KM, Pence BW, Aiello A, and Robinson W.

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AAP	American Academy of Pediatrics
ACA	Affordable Care Act
BLS	Bureau of Labor Statistics
BMF	Breast milk feeding
CDC	Centers for Disease Control and Prevention
CI	Confidence interval
DAG	Directed acyclic graph
DHHS	Department of Health and Human Services
EBF	Exclusive breastfeeding
HR	Hazard ratio
IFPS II	Infant Feeding Practices Survey II
IP	Inverse-probability
NICU	Neonatal intensive care unit
TPB	Theory of Planned Behavior
RR	Risk ratio
WHO	World Health Organization

CHAPTER 1: REVIEW OF THE LITERATURE

Introduction

Breastfeeding durations in the U.S. fall well short of recommendations (Centers for Disease Control (CDC) 2016). Exclusive breastfeeding is recommended for six months and continued breastfeeding for one (American Academy of Pediatrics (AAP) 2012) or two years and beyond (World Health Organization (WHO) 2011). However, as recently as 2013, only 22% of infants born in the U.S. were exclusively breastfed for six months, and 31% were still breastfed at 12 months (CDC 2016). In 2015, nearly 55% of all mothers with a child under one year of age were working in the U.S. (Bureau of Labor Statistics (BLS) 2016). Employed mothers have lower initiation rates and shorter durations of breastfeeding than those who are unemployed (Department of Health and Human Services (DHHS) 2011). Nearly half of working mothers returned to work within eight weeks of taking parental leave (Klerman *et al.* 2014). In order for mothers to continue producing milk, they must regularly express milk from their breasts at intervals corresponding to their infants' feeding patterns.

Policy and workplace solutions to this dilemma promote breast pumping among working mothers (AAP 2013; DHHS 2009). However, many mothers work in places that do not provide time and a clean space for them to pump because those workplaces are exempt from the related protections in the Affordable Care Act (ACA). In addition, employees are sometimes not aware of the breastfeeding policies at their place of work (Kozhimannil *et al.* 2016). Mothers often

have to negotiate special arrangements at their workplaces in order to pump breast milk, and plan their workdays carefully to allow for the breaks they need. Managers and peers may or may not be supportive of special arrangements, however temporary, potentially creating a discouraging environment for mothers who want to continue breastfeeding (Stewart-Glenn 2008). Taking unpaid breaks to pump breast milk lengthens a mother's workday, which increases her time away from her infant and, potentially, her childcare costs. Due to the physical, psychological and logistical burdens that combining regular pumping with working imposes on mothers in the early postpartum period, breast pumping may not increase breast milk feeding (BMF; includes feeding expressed breast milk and feeding at the breast) duration. The literature shows mixed evidence for an association of pumping with BMF duration (Johns *et al.* 2013). A better understanding of the impact of regular pumping in the early postpartum period on BMF duration is critical to ascertaining if workplace policies that support breastfeeding through breast pumping actually help mothers to increase their breastfeeding duration and achieve their breastfeeding goals.

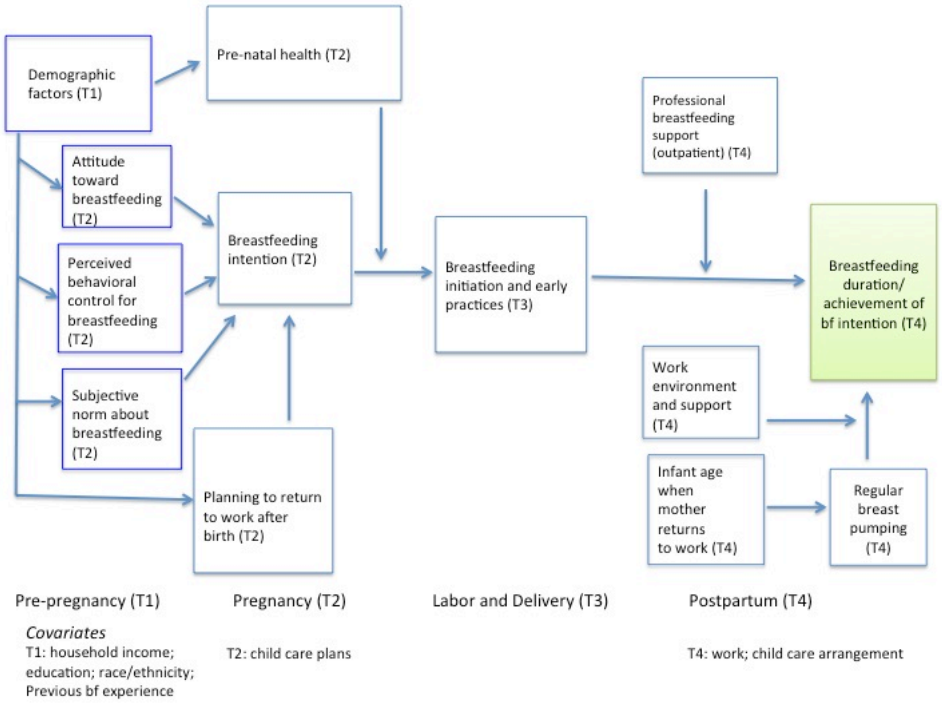
1.1 Conceptual Framework

Prenatal intention to breastfeed is a strong predictor of breastfeeding outcomes (Bonuck *et al.* 2005; Bai *et al.* 2011). The Theory of Planned Behavior (TPB) posits that intention precedes behavior, and has underpinned a few breastfeeding studies, which did not differentiate between breastfeeding and BMF (e.g., Duckett *et al.* 1998; Bai *et al.* 2010). The assumption is that an intention results from all of the motivational forces to perform a behavior (Ajzen 1991). TPB's premise is that one's attitude toward the behavior, perceived behavioral control, and subjective norm (the beliefs of key influencers and the importance of their beliefs to the subject) influence behavior by affecting one's intention (Ajzen 1991; Wambach 1997). Bai *et al.* found that those three factors accounted for most of the variability in mothers' intentions to exclusively

breastfeed (Bai *et al.* 2010). Breast milk pumping is an accessory behavior that is on the pathway between a woman's breastfeeding intention and her achieving that intention if she will be separated from her infant. How breast milk pumping affects BMF duration and achieving BMF intentions has been understudied.

This study examined how regular pumping in the early postpartum period influenced BMF and exclusive BMF duration and achievement of breastfeeding intention. Although I did not specifically test the role of components or pathways postulated by the TPB, it provided a useful theoretical framework for my analyses (Figure 1). I considered covariates measuring women's attitudes, subjective norms and perceived behavioral control to BMF in my causal frameworks (Section 3.2). In addition, the model depicts some of the complexity inherent to a woman's decisions during this time, e.g., a woman's plans to return to work affect her BMF intention because she anticipates a certain work environment and level of support at her workplace.

Figure 1. Conceptual model for this study, incorporating the Theory of Planned Behavior



The conceptual model shows that demographic factors influence the three main factors that affect breastfeeding intention (attitude, behavioral control and subjective norm), along with prenatal health and plans to return to work (measured at times (T) 1 and 2). Intention affects early practices (T3), which ultimately affect duration and achievement of intention (T4). Both prenatal health (T2) and accessing professional support (T4) influence that pathway. Regular pumping (T4) also affects breastfeeding duration and achievement of intention on a pathway affected by infant age (T4) and work environment and support (T4). Additional covariates are noted at their respective time points at the bottom of the diagram.

1.2 Critical review of literature

Breastfeeding conveys specific benefits to mothers, infants, and society

The WHO and the AAP recommend exclusive breastfeeding through six months, with continued breastfeeding for at least 12 (AAP 2012) or 24 months and beyond (WHO 2011). Exclusive breastfeeding (EBF) is when an infant consumes nothing other than breast milk and it conveys health benefits to mothers and infants, including delayed return to fertility for mothers, and reduced risks of diarrheal disease, respiratory illness, and ear infections for infants (WHO 2011; Kramer & Kakuma 2012; Bachrach *et al.* 2003; Ladomenou *et al.* 2010. EBF increases the likelihood of continued breastfeeding through one year (AAP 2005). Continued breastfeeding further benefits infants and mothers: reduced risk of postpartum depression, type II diabetes, breast and ovarian cancers for mothers, and reduced risk of mortality, asthma, obesity, malocclusion and ear infections for infants and children, along with higher IQ (Grummer-Strawn & Rollins 2015). If 80% of families in the U.S. could breastfeed exclusively for six months, the U.S. would save $10.5 billion per year and prevent 741 deaths, mainly in infants (Bartick & Reinhold 2010). Other societal benefits include: decreases in health costs (Weimer 2001; Ball &

Wright 1999; Bartick *et al.* 2013); public spending on assistance programs (Tuttle & Dewey 1996); employee absenteeism for parents and related lost income (Cohen *et al.* 1995); reduced environmental burden for disposal of bottles and formula packaging, and reduced energy demands to create and transport those products (Jarosz 1993; Levine & Huffman 1990).

Breastfeeding prevalence in the U.S. falls far short of recommendations, contributing to health disparities between rich and poor.

Despite WHO and AAP recommendations, in 2012 only about 22% of infants born in the U.S. were exclusively breastfed for the first six months of life. In addition, only about 30% of infants were breastfed for 12 months (CDC 2015). Suboptimal breastfeeding practices have been cited as both an outcome and cause of health and social disparities in developed countries because low-income families currently have lower rates of breastfeeding than wealthy families, a pattern perpetuated across recent generations (University of Sheffield 2016; Bolling *et al.* 2007). Breastfeeding affects a child's long-term health and development; consequently, sub-optimal breastfeeding practices among low-income families increase their burden of adverse health outcomes (University of Sheffield 2016). Breastfeeding can redress health disparities by lowering the risk of illness for poor children. In addition, evidence suggests that infants breastfed for at least one year had more education and higher earnings at age 30 than infants breastfed for less than one month, controlling for family income (Victora *et al.* 2015). However, some researchers found that mothers who breastfed for six or more months had longer and more severe income losses than mothers who breastfed for shorter durations or not at all (Rippeyoung & Noonan 2012), suggesting that mothers may need a certain level of financial security to breastfeed optimally.

Nearly half of working mothers returned to work within eight weeks of birth; 22% returned within two weeks (Klerman *et al.* 2014).

In the U.S. 66% of mothers having a first birth between 2006 and 2008 reported being employed during pregnancy (Laughlin 2011). Prenatal employment predicts postpartum return to work: over 58% of women who worked during pregnancy returned to work within three months; about 15% of mothers who did not work during pregnancy started working by three months postpartum (Laughlin 2011). This timing of return to work coincides with the recommended timeframe for breastfeeding. Trends in mothers working after their first birth increased rapidly over the past 50 years, with little change in the past decade (Laughlin 2011).

In 2015, nearly 55% of all mothers with a child under one year of age were working in the U.S. and most of them worked more than 35 hours per week (BLS 2016). Forty percent of mothers are the primary breadwinner in their household (Wang *et al.* 2013). Low-wage jobs are predominantly held by women (National Women's Law Center 2014). Employed mothers have lower initiation rates and shorter durations of breastfeeding than those who are unemployed (DHHS 2011).

Despite the documented benefits of breastfeeding and recommendations for exclusive and extended breastfeeding, prevalence of both practices is low in the U.S. due to individual and structural barriers, including mothers' return to work.

Data on factors that negatively affect EBF, specifically, are sparse; the only documented factor associated with EBF in the U.S. is higher maternal age (Jones *et al.* 2011). There are more data about breastfeeding in general: individual factors that may be negatively associate with breastfeeding are non-white race, low birth weight, young maternal age, poor mental or emotional health, lack of knowledge about breastfeeding, embarrassment, no intention to breastfeed, and lactation problems (DHHS 2011; Jones *et al.* 2011; Donath *et al.* 2003). Social and structural factors that may negatively impact breastfeeding in addition to maternal

employment include lack of knowledge in the general population, social norms, poor social support, health care practices that separate mother and infant after birth, and child care provider practices (DHHS 2009; Cohen *et al.* 1995).

Some studies found an increased risk of no breastfeeding with full-time employment (Mandal *et al.* 2010; Ogbuanu *et al.* 2011; Ryan *et al.* 2002); another did not (Chatterji & Frick 2005). One mechanism through which working could affect exclusive BMF duration is job autonomy, which is the ability to determine when, where, and how work is completed. Mothers need flexibility in order to feed infants on demand through either direct breastfeeding or expressing breast milk, and mothers also need time to complete either of those tasks. Lack of job autonomy may reduce exclusive BMF duration by limiting a mother's ability to breastfeed or to express breast milk when necessary. In addition, limited job autonomy may affect a mother's intention to EBF prior to returning to work if she anticipates difficulty with scheduling breaks upon her return. This mechanism could also change a mother's intention to EBF after she returns to work if she encounters challenges related to securing adequate break time.

In the U.S., women employed full-time during their pregnancies were less likely to meet their intention of EBF than women who were not employed during pregnancy (Attanasio *et al.* 2013). Returning to work could change a mother's prenatal breastfeeding intention. Evidence suggests that returning to work full-time before their infants were three months old may reduce mothers' abilities to meet intentions to breastfeed for at least three months (Perrine *et al.* 2012). Further, mothers who planned to return to work before three months postpartum or who returned to work full-time were less likely to intend to EBF than mothers returning to work after three months or returning part-time (Mirkovic *et al.* 2014). This is not a phenomenon unique to the U.S.: a study in Hong Kong showed that breastfeeding intention was 85% but only 60% met that

intention; nearly 30% of mothers who stopped breastfeeding cited returning to work as their reason for weaning (Wang *et al.* 2014). Likewise, 60% of women in an Australian study intended to breastfeed after returning to work but only 40% did so (Weber *et al.* 2011).

Only one study has examined the relationship between maternal occupation and breastfeeding in the U.S., and found that women working in administrative and manual occupations were more likely to stop breastfeeding earlier than professional women, women working in service industries, and stay-at-home-mothers, suggesting a differential association between occupation and breastfeeding (Kimbro 2006). Occupation-related obstacles to EBMF likely disproportionately affect lower-SES mothers who return to work in the early postpartum period and whose limited autonomy in the workplace is determined by occupation and other social factors like education. In addition, more women in some racial/ethnic groups work in service industry than in professional occupation categories (BLS 2013). Erratic work schedules are a particular problem for combining low-wage jobs with breastfeeding (Carothers & Hisgen 2016), in addition to limited break time associated with hourly employment and job responsibilities related to continuous customer service (Kozhimannil *et al.* 2016). In addition, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (commonly called "welfare reform") requires mothers to work when their infants are a few months old; that has been estimated to decrease the national breastfeeding rate, overall (Haider *et al.* 2003), and has particular personal consequences for the most vulnerable women and infants.

To address workplace barriers, the ACA mandates unpaid break time and a private place (other than a bathroom) for women to pump breast milk, but the impact on breastfeeding practices has been understudied.

The ACA also requires health insurance companies to support breast pump rental and purchase and breastfeeding education and counseling (AAP 2013). However, current federal

protections for breastfeeding in the workplace do not cover all workers, e.g., exempt employees and those working for an employer with fewer than 50 employees (AAP 2013; Kozhimannil *et al.* 2016). Some Medicaid recipients and women in the Women, Infants and Children (WIC) program are also not covered by workplace and insurance coverage provisions that support breastfeeding (Hawkins *et al.* 2015). Thus, many mothers must choose between working and breastfeeding. One study using data from a national survey of women who gave birth in 2011 and 2012 found that only 40% of mothers had access to both break time and private space, as stipulated in the ACA (Kozhimannil *et al.* 2016). Women who had both break time and private space were 2.3 times as likely to EBMF to six months than women without (Kozhimannil *et al.* 2016).

Contextual factors like paid maternity leave (Ogbuanu *et al.* 2011), supportive policies at government and workplace (Fein *et al.* 2008; Ortiz *et al.* 2004), and individual-level support from a supervisor or workplace peer cohort (Johnston & Esposito 2007) have been found to affect breastfeeding initiation, duration or intensity; these are the types of interventions that policymakers and industry leaders could consider ensuring on a wider scale.

Breast milk pumping challenges conventional research on infant feeding, and its effect on health is unknown.

There is increasing recognition of breast milk pumping as a phenomenon that challenges conventional assumptions about breastfeeding, which heretofore had been assumed to be directly feeding from a breast. Imprecise definitions differentiating breastfeeding from breast milk feeding have thwarted attempts at systematic review (Johns *et al.* 2013). There is a call for a new specificity in language and data collection to document infant feeding practices, given the increasing prevalence of pumped milk feeding and the recognition of particular hazards and benefits associated with the practice (Geraghty & Rasmussen 2010; Geraghty *et al.* 2012;

Rasmussen & Geraghty 2011), which may include increased bacteria in pumped milk, reduced ascorbic acid concentration, reduced antioxidant activity, hydrolyzed lipids, and lyzed immunological cells, although the impact of these changes in milk on infant health is not yet understood (Rasmussen & Geraghty 2011).

Use of bottles to feed expressed milk can introduce harmful bacteria if the different components of the bottles and of the pump itself are not adequately sanitized (Rasmussen & Geraghty 2011). In addition, bottle-feeding may promote a caregiver's behavior that encourages finishing a bottle regardless of infant satiety. Infants fed breast milk in a bottle early in life had a greater likelihood of emptying a bottle later in life, regardless of whether the later bottle contained formula or breast milk (Li *et al.* 2010). More research is needed to determine if infants fed expressed breast milk are fed differently or grow differently than their counterparts (Rasmussen & Geraghty 2011). In addition, breast milk changes composition over time and during the course of a feeding and some evidence suggests that infants may develop diarrhea and fail to thrive if they receive an imbalanced proportion of breast milk, e.g. if most pumped milk is typically higher in fat than milk received at the breast and infants receive an imbalanced proportion of one to the other (Woolridge & Fisher 1988; Rasmussen & Geraghty 2011). Increased infant illness could increase employee absenteeism and a change in infant feeding practice, including abandonment of breastfeeding (Nelson *et al.* 1997).

Prevalence of breast milk pumping is increasing, but its effect on BMF and exclusive BMF duration and achievement of breastfeeding intention among mothers returning to work in the early postpartum period is unknown.

Despite uncertainty of health effects, breast milk pumping for healthy, term infants is increasing (Johns *et al.* 2013). Many working mothers use breast pumps, which are covered by health insurance as a result of the 2010 Affordable Care Act. In Maine alone, there was an 11-

fold increase in private insurance claims for breast pumps between 2012 and 2014, although there were only 11 claims for breast pumps from Medicaid recipients over the same period (Hawkins *et al.* 2017). The most recent estimates of breast milk expression among a U.S. cohort of mothers (measured prior to the ACA) suggest that 85% of breastfeeding mothers of infants aged 1.5 to 4.5 months expressed milk at some time; 25% of them had done so on a regular schedule in the previous two weeks, and expressing milk on a regular schedule was associated with maternal employment and use of an electric pump (Labiner-Wolfe *et al.* 2008). Mothers who pump may differ from those who don't: one study suggests they have higher household income, are employed and have no previous breastfeeding experience, compared to mothers who did not express milk (Labiner-Wolfe *et al.* 2008).

Mothers may pump their milk because they think it will allow them to continue breastfeeding longer than they would if they had not pumped (Rasmussen & Geraghty 2011). There is mixed evidence regarding the association of pumping with breastfeeding duration. A study in Cincinnati found that 63% of mothers began milk expression by the end of the first month, and predictors of early expression included planned work by six months, lower birth weight, and higher maternal body mass index, but early expression did not influence the duration of breast milk feeding (Geraghty *et al.* 2012). Low-income mothers in California who were given a breast pump requested formula four months after mothers who did not receive a pump (Meehan *et al.* 2008). Two studies in Australia support the notion that breast milk expression can increase breast milk feeding duration: mothers who ever expressed milk were more likely to continue breastfeeding to six months than mothers who never expressed (Win *et al.* 2006) and some mothers reported breastfeeding longer because they expressed milk (Clemons & Amir 2010). However, a study in Shanghai found that mothers who exclusively expressed breast milk at six

weeks had shorter breast milk feeding durations than mothers who fed only at breast and mothers who both fed at breast and expressed breast milk (Jiang *et al.* 2015). Recent evidence suggests that mothers who pump for non-elective reasons including difficulty feeding at the breast and employment have shorter breastfeeding durations than mothers who pump electively, and mothers who pump more frequently had shorter breast milk feeding durations (Felice *et al.* 2016). In addition, early termination of breastfeeding has been associated with the effort required to continually pump milk, contributing to 60% of mothers ending breastfeeding earlier than they had intended (Odom *et al.* 2013).

There are potential physical, psychological and logistical burdens that combining regular pumping with working imposes on mothers in the early postpartum period, a time when women are recovering from childbirth, navigating changes in relationships and roles, possibly experiencing postpartum depression, managing infant health issues (Chatterji & Frick 2005), and resuming work and workplace relationships after an absence. Although lactation can suppress physiological stress responses, increased psychological stress could hinder lactation through its effects on serotonin, by inhibiting prolactin and oxytocin, or by activating a sympathetic central nervous system response, and stress has been found to interfere with lactation (Lau 2001).

1.3 Summary

Breastfeeding benefits mothers and infants, both in the immediate term and over the life course, and is a behavior that is subject to psychosocial and environmental influences. A mother's return to work can be a barrier to breastfeeding if she is separated from her infant for an extended period of time. The federal government and many workplaces promote expressing breast milk (pumping) as a way for mothers to continue breastfeeding while working away from their infants, but it is not known if regular pumping increases breast milk feeding duration for

mothers returning to work in the early postpartum period and enables them to achieve their prenatal breastfeeding intentions.

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CHAPTER 2: STATEMENT OF SPECIFIC AIMS

Section 2.1 Specific aims

Aim 1: Compare the hazards of discontinuing BMF between regular and non-regular pumpers: overall, and for working and non-working women

Aim 1a: Compare the hazards of discontinuing exclusive BMF between regular and non-regular pumpers: overall, and for working and non-working women

Aim 2: Compare the risks of not achieving prenatal intentions for duration of BMF between regular and non-regular pumpers: overall, and for working and non-working women

Aim 2a: Compare the risks of not achieving prenatal intentions for duration of exclusive BMF between regular and non-regular pumpers: overall, and for working and non-working women

Section 2.2 Hypotheses

Hypothesis 1: Mothers who regularly pump and work will have shorter BMF durations than other mothers.

Hypothesis 1a: Mothers who regularly pump and work will have shorter exclusive BMF durations than other mothers.

Hypothesis 2: Mothers who regularly pump and work will have a greater risk of not meeting their prenatal intention for BMF duration than other mothers.

Hypothesis 2a: Mothers who regularly pump and work will have a greater risk of not meeting their prenatal intention for exclusive BMF duration than other mothers.

Section 2.3 Rationale

Associations between breast milk pumping and both BMF duration and achievement of BMF intentions are unclear in the literature. At the same time, it is important to understand these relationships because current policies support BMF among working women mainly through support for pumping. The significance of this study is that it examines the association of early, regular pumping with BMF duration among a cohort of mothers, some of whom resumed work before their infants were two months old, which is the situation for about 45% of working mothers in the U.S. It is the first examination of this association using a time-to-event approach and controlling for a range of relevant confounders that is undergirded by the TPB. This study provides important information to contextualize policy discussions about breast pumping as an alternative to direct breastfeeding, especially for mothers returning to work in the early postpartum period. This information could be used to evaluate policies that encourage early, regular pumping for working mothers, as well as the expectation that breast pumping will improve national breastfeeding rates, which is implied by the ACA and workplace policies aimed at supporting women to continue breastfeeding while they are separated from their infants.

I hypothesized that early (within the first two months), regular pumping would be associated with shorter BMF and exclusive BMF durations among working women because of the physical, psychological and logistical burdens of regular pumping while working in the early postpartum period. I further hypothesized that working women who began regular pumping within the first two months would be less likely to achieve their prenatal breastfeeding intentions than other women, including those who worked but did not pump regularly, those who did not work but pumped regularly, and those who neither worked nor regularly pumped.

This study is innovative because it uses the Theory of Planned Behavior to guide the first prospective assessment of the association between early, regular pumping and BMF and exclusive BMF durations among both working and non-working women in the U.S., and achievement of their prenatal BMF and exclusive BMF intentions. It will provide information to contextualize policy discussions about breast pumping as an alternative to direct breastfeeding among working mothers, particularly those returning to work in the early postpartum period. This information can be used to evaluate the expectation that breast pumping will improve breastfeeding rates, which is implied by the ACA and workplace policies aimed at supporting women to continue breastfeeding while they are separated from their infants.

CHAPTER 3: METHODS

Section 3.1 Overview of Methods

These cohort studies examine the influence of regular pumping in the early postpartum period on two key breastfeeding outcomes: 1) time to cessation and 2) achievement of intention. For Aim 1, I used a time-to-event analysis to estimate hazard ratios for discontinuing BMF and exclusive BMF for regular pumpers compared to non-regular/non-pumpers. I calculated and applied drop-out weights for all observations to address selection bias caused by women who were lost to follow up. For Aim 2, I estimated risk ratios for achieving breastfeeding intention for regular pumpers compared to non-regular/non-pumpers. For both Aims, I calculated and applied selection weights to address potential bias. I also calculated and applied inverse-probability weights to control confounding and tested suspected effect measure modifiers. Both studies use data from the IFPS II, a longitudinal study conducted by the CDC and the FDA from 2005-2007.

Section 3.2 Design

Subject identification and sampling

Source Population: CDC and FDA conducted the Infant Feeding Practices Study II (IFPS II) in 2005–2007. It was a longitudinal study focusing on infant feeding practices through the first year of life as well as the diets of women before and after birth. Infant feeding includes breastfeeding, formula feeding, solid food intake, and other complementary foods and liquids. There was also a

follow-up survey of participants in 2012 (CDC 2014). More than 32 studies have been published using these data: http://www.cdc.gov/breastfeeding/data/ifps/publications.htm

The sampling frame comprised a national consumer opinion panel of 500,000 households throughout U.S. The consumer panel did not calculate sampling weights because these data are not representative of any given population. To participate, a mother must have been at least 18 years old with a singleton infant born at ≥35 weeks' gestation, weighing at least 5 lbs., and without medical conditions that would affect feeding (n=4902 pregnant women beginning the study; about 2000 continued through infant's first year) (Fein *et al.* 2008).

IFPS II was conducted with monthly mail questionnaires in addition to a brief telephone interview near the time of the infant's birth. The survey began in the third trimester and collected data monthly through the infant's first year. Mothers who completed the prenatal questionnaire but did not meet study inclusion criteria after their infants' births were disqualified. In addition, respondents residing in a zip code to which mail was not delivered due to Gulf Coast hurricanes in 2005 were also excluded. Respondents' data were included through the questionnaire on which they were disqualified.

Each participating mother received a Neonatal Questionnaire mailed 2 to 4 weeks after the baby's birth. This was followed by nine questionnaires mailed approximately monthly. Table 1 shows the actual infant ages when the questionnaires were completed; Table 2 shows the topics addressed by each questionnaire (CDC 2012). Specifically, combinations of eight modules were mailed to mothers monthly from the time an infant was two months through seven months of age, then three times (every 7 weeks) until the infant reached 12 months of age (CDC 2014). The consumer panel policy provided for participants to receive a small gift (less than $3) for each

completed questionnaire (not including the Diet History Questionnaire, which was administered twice and compensated at $10 each.) (Fein *et al.* 2008).

Although each questionnaire was targeted to reach mothers when infants were a certain age, infants' ages when questionnaire was completed do not always match and CDC attempted to move infants into the correct age groups. The median age matches the target ages but the 10th and 90th percentiles show that some infants were older or younger than the target age.

Demographic data were collected in two ways. Most mothers' data came from a panel database. A demographic questionnaire was routinely sent to consumer opinion panel members by the panel administration. However, if a mother lived in the house of a panel member but was not the panel member herself, she was sent a separate demographic questionnaire. Mother's age and parity come from the prenatal questionnaire.

Response after the prenatal questionnaire ranged from 63% to 83% for the various questionnaires: 1,813 completed at least 10 of 12 questionnaires (CDC 2012). Participants were not excluded if they did not return one or more questionnaires (Fein *et al.* 2008).

A comparison of IFPS II respondents to a nationally representative sample of new mothers in the National Survey of Family Growth Cycle 6 (1998 – 2000) indicated that the IFPS II sample was older, more highly educated, less likely to be low income, more likely to be employed, more likely to be white, had fewer other children, less likely to be from South, less likely to smoke, took longer maternity leave, and received first prenatal care a little later in pregnancy than nationally-representative sample (CDC 2012; Fein *et al.* 2008). In addition, breastfeeding practices were compared to a National Immunization Survey sample of women who gave birth in 2004. IFPS II mothers were more likely to breastfeed overall and to breastfeed longer than mothers in the general population (Fein *et al.* 2008).

Implausible values were changed to "missing." Date of questionnaire completion and age of infant when mother completely stopped breastfeeding were imputed if missing. Data collection staff indicated when the questionnaire was mailed and when it was returned. Imputed dates of questionnaire completion were based on the average number of days between questionnaire completion and the date of the receipt of the questionnaire for those who filled in the date (Fein *et al.* 2008). To impute a missing age of infant when breastfeeding ceased, the study team assessed whether a previously breastfeeding mother indicated no breast milk on an infant food frequency question, and then used the mean infant age between the last time the infant was reported to be breastfeeding and the age when the infant was first reported not breastfeeding (Fein *et al.* 2008). CDC shifted all dates on questionnaires by a random interval to assure each individual's anonymity, and shifted all dates for a given respondent by the same interval to maintain relations between dates.

Selection Criteria: The parent study cohort included 3033 women who were 18 years or older in the third trimester and delivered a singleton infant weighing at least 5 lb., and completed the neonatal survey. In addition, the infant had to have 35 weeks or more gestation and spent three or less days in the neonatal intensive care unit (CDC 2012). From the parent study cohort (n=3033), I selected all women who reported BMF on the questionnaire at month 2 (n=1624), which is when the exposure (regular pumping) was measured (Aim 1: first analysis). For the second analysis (Aim 1), I selected women who reported exclusive BMF when they completed the questionnaire month 2 (n=971) from the original study cohort (n=3033). BMF and exclusive BMF were determined by responses to food frequency questions (CDC 2012). When her infant consumed breast milk only, I considered a woman to be exclusively BMF (CDC 2012).

For the first analysis of Aim 2, I selected women who 1) reported a BMF intention when they completed the prenatal questionnaire; and 2) reported BMF on the questionnaire at month 2, when the exposure (regular pumping) was measured (n=1512) from the parent study cohort (n=3033). For the second analysis (Aim 2), I selected women who 1) reported an exclusive BMF intention when they completed the prenatal questionnaire; and 2) reported exclusive BMF on the questionnaire at month 2, when the exposure (regular pumping) was measured (n=867) from the parent study cohort (n=3033). I considered a woman to be exclusively BMF when her infant consumed only breast milk (CDC 2012).

Methods for studies

Classification of exposure: The exposure for all of these studies is "regular pumping," (including any form of breast milk expression, but not further defined on the questionnaire) that began when the infant was less than nine weeks old. Mothers indicated regular pumping in response to this question on the 2-month questionnaire: "Are you now pumping milk on a regular schedule?" (answer: yes/no) which was posed to all mothers who indicated a value greater than 0 on the filter question: "During the past 2 weeks, how many times did you pump milk?" (answer: numeric value; CDC 2014). Mothers were then asked, "How old was your baby when you first began pumping milk on a regular schedule?" (CDC 2014). All mothers who indicated that they began pumping milk on a regular schedule when their infant was less than nine weeks old were considered exposed ("regular pumpers"). All mothers who indicated the value 0 in the filter question, responded "no" to the question of regular pumping, or indicated beginning regular pumping when their infant was nine weeks of age or older were considered unexposed ("non-regular/non-pumpers"). Less than 10% of survey questionnaires intended to be completed around month 2 (~8.6 weeks) were completed one or more months later (13 or more weeks after birth).

Classification of outcome (Aims 1 and 1a): I do not distinguish between direct breastfeeding and expressing milk for feeding. Although there is a growing body of research that distinguishes between these practices and the outcomes of these practices (e.g., Geraghty & Rasmussen 2010), the IFPS II survey did not distinguish between the two practices when ascertaining breastfeeding duration. The outcome for Aim 1 is time to BMF cessation, which was measured in terms of time to cessation of breastfeeding and breast pumping. Each monthly questionnaire contained a module for mothers to complete when they ceased all breastfeeding and breast milk pumping. Respondents are guided through that module upon answering this filter question affirmatively: "Have you completely stopped breastfeeding and pumping milk for your baby?" (answer: yes/no; CDC 2014). Respondents indicated the age of their infants when the mother stopped breastfeeding and pumping milk (not necessarily when the infant stopped receiving breast milk). Thus, BMF duration for this analysis is a measure of the mother's practice.

CDC imputed missing values for BMF duration, which comprised approximately 6% of the parent study population (CDC 2012), and which I used in my analyses. If a mother stopped participating in the study, then she was censored and her BMF duration was equal to her infant's age when she completed her last survey. Women who BMF for more than the minimum recommended duration were censored at the time of the recommended duration (six months for exclusive BMF and 12 months for BMF; AAP 2012).

The outcome for Aim 2 is time to exclusive BMF cessation, which was measured as time to infant consumption of food other than breast milk. Exclusive BMF was measured on each questionnaire through food frequency questions (CDC 2012). I used the IFPS II variable for exclusive BMF duration, which estimates infant age at the mid-point between the last questionnaire on which the mother was exclusive BMF and the first questionnaire on which she

was not. I censored mothers when they stopped participating in the parent study, and made their exclusive BMF durations equal to infants' ages when their last surveys were completed.

Classification of outcome (Aims 2 and 2a): The outcomes were achievement of BMF (Aim 2) and exclusive BMF (Aim 2a) intentions. Mothers reported intended durations on the prenatal questionnaire in response to: "How old do you think your baby will be when you completely stop breastfeeding?" (answered in months) and "How old do you think your baby will be when you first feed him or her formula or any other food besides breast milk?" (answered in categories: less than one month; 1 to 2 months; 3 to 4 months; 5 to 6 months; 7 to 9 months; more than 9 months; CDC 2014). Thus, "achievement of BMF intention" refers to the comparison between when mothers' stopped breastfeeding and pumping milk and when they stated that they would stop breastfeeding. I created a variable to indicate if a woman achieved her intention. For Aim 2a, I used the IFPS II dataset variable for exclusive BMF duration and created a variable that compared exclusive BMF duration to intended exclusive BMF duration, to indicate if a woman achieved her exclusive BMF intention.

Classification of covariates: I created a DAG of covariate relationships using literature, the Theory of Planned Behavior, and expert consultation, and analyzed it with Dagitty v.2.3. That analysis yielded a minimally sufficient adjustment set of confounders (Figure 2; Table 1).

Infant formula use is included in Figure 2 (Aims 1 and 2) but not Figure 3 (Aims 1a and 2a), since it cannot co-exist with exclusive BMF. That is the only difference between Figures 2 and 3. In addition, although the outcome is different for Aims 1 and 2 (time to BMF cessation and achievement of BMF intention), the same covariate relationships apply to both outcomes. The same is true for Aims 1a and 2a.

Figure 2: DAG for Aims 1 and 2 (showing outcome for Aim 1).

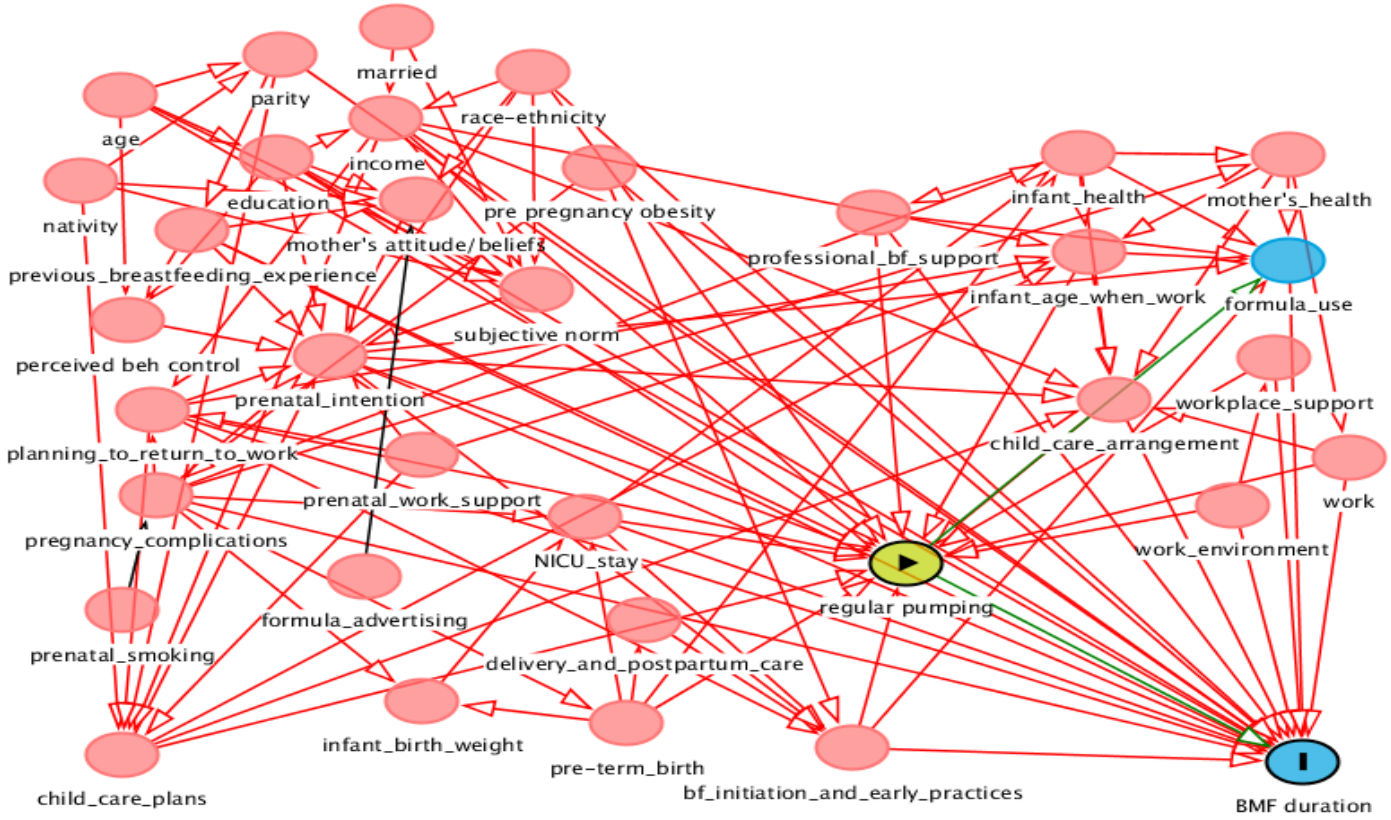


Figure 3: DAG for Aims 1a and 2a (showing outcome for Aim 1a).

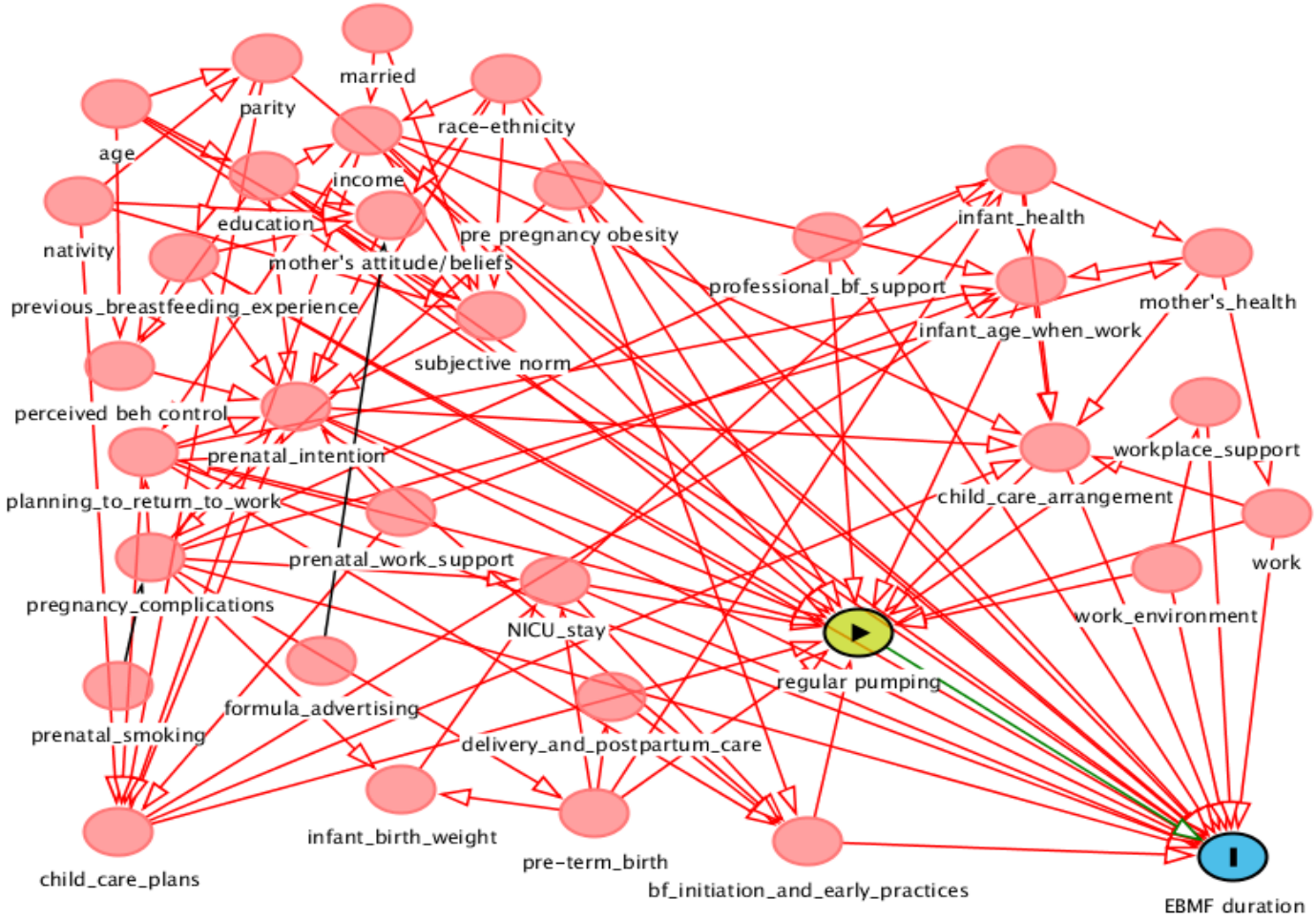


Table 1: Covariate descriptions, all Aims

Variable[a]	IFPS II Survey questions and responses (CDC, 2014)	Time of collection	Specification for this study
Demographic characteristics			
Household income	27 categories ranging from less than $5000 to $300,000 and over	Prenatally[b]	Continuous
Education	Response categories: 1: 1-7 years grade school 2: 8 years grade school 3: 1-3 years high school 4: high school graduate 5: 1-3 years college 6: College graduate 7: Post graduate	Prenatally[b]	Dichotomized to: less than a college degree and college degree or higher
Race-ethnicity	Response categories: 1: White 2: Black 3: Hispanic 4: Asian/Pacific Islander 5: Other	Prenatally[b]	Dichotomized to: white, non-Hispanic and other due to small numbers in other categories
Previous breastfeeding experience	"Did you breastfeed, for any time at all, any of your other babies?" Answer choices: yes or no.	Prenatally[b]	Same as IFPS II; primigravida=no.
Prenatal factors			
Prenatal intention to breastfeed	"How old do you think your baby will be when you completely stop breastfeeding?" Answer in month range (exclusive) and months (any).	Prenatal questionnaire[c]	Same as IFPS II; continuous
Planning to return to work	"Do you plan to work for pay during your baby's first year" (yes/no). For those who reply "yes": "How many weeks after the	Prenatal questionnaire[c]	Dichotomized to match exposure timeframe (as closely as possible): within the first 9 weeks, or later.

	baby is born do you plan to return to work?" Response categories: 1: Fewer than 4 weeks 2: 4 to 6 weeks 3: 7 to 9 weeks 4: 10 to 12 weeks 5: 13 to 16 weeks 6: 17 to 20 weeks 7: 21 to 30 weeks 8: More than 30 weeks		
Child care plans	"What will you do with your baby when you are working?" Response categories: 1: My baby will be cared for by a family member 2: My baby will be cared for by someone not in my family 3: I will keep my baby with me while I work outside my home 4: I will keep my baby with me while I work at home 5: I have not decided yet	Prenatal questionnaire[c]	Three categories, continuous: • mother and infant are not separated; • mother is unsure about her child care plans or mother reports a combination of separated and non-separated choices; • mother and infant are separated
Labor and delivery (hospital or birth center) factors			
Breastfeeding initiation and early practices	a. Newborn pacifier use: "Was your baby given a pacifier by you, the medical staff, or anyone else while in the hospital or birth center?" Answer choices are yes, no, or don't know. b. Time to first breastfeed: "About how long after your delivery did you breastfeed or try to breastfeed your baby for the very first time?" Response categories:	Neonatal questionnaire[d]	This variable combines responses to six questions about breastfeeding initiation and early practices that occurred in the hospital or birth center. Thus, this continuous variable (range: 0 – 6) equally weights the following issues that can lead to suboptimal feeding practices. Each undesirable response garners one point. a. Newborn pacifier use: this can prevent optimal breastfeeding if infants expend too much energy sucking on the pacifier rather than the breast and

	1. less than 30 minutes 2. 30 to 60 minutes 3. 1 to 2 hours 4. 3 to 6 hours 5. 7 to 12 hours 6. 13 to 24 hours 7. 1 day 8. 2 days 9. more than 2 days c. Feeding infant other substances: "While you were in the hospital or birth center, was your baby fed water, formula, or sugar water at any time?" Answer choices included yes, no, and don't know. d. Rooming in: "While you were in the hospital or birth center, did your baby stay in your room day and night, except for doctor visits, bathing, or other treatments?" Answer choices were yes, all the time; yes, some nights but not all; or no. e. Support for breastfeeding: "While you were in the hospital for delivery of this baby, did anyone help you with breastfeeding by showing you how or talking to you about breastfeeding?" (yes/no) f. Post-partum referral for support: "Were you given information about any breastfeeding support groups or services before you went home		if pacifier sucking contents them to the extent that mothers cannot recognize hunger signals and too much time elapses between feedings. Answers "yes" and "don't know" get one point. b. Time to first breastfeeding: Breastfeeding should be initiated within the first hour of life. Any response greater than one hour garners one point. c. Feeding infant other substances: Feeding infants anything other than a mother's early milk (colostrum) could affect breast milk feeding practices. Answers "yes" and "don't know" get one point. d. Rooming in: Infants are more likely to breastfeed when they stay in their mothers' rooms. Answers "yes, some nights but not all" and "no" get one point. e. Support for breastfeeding: "No" responses get one point. f. Post-partum referral for support: "No" responses get one point. g. Infant formula gift bag: Gift bags that promote formula use discourage breastfeeding. Responses indicating receipt of infant formula or a coupon for infant formula will get one point.

	from the hospital or birth center?" (yes/no) g. Infant formula gift bag: "Did you receive a gift pack or diaper bag from the hospital or birth center? Include a gift pack from a child birth class if you took the class at the hospital or birth center." (yes/no). For those responding "yes": "Were any of the following included in the gift pack? If you received more than one gift pack from the hospital or birth center, answer for all that you received." Response categories: 1: Infant formula 2: Coupon for infant formula 3: Breastfeeding supplies (nursing pads, nipple cream, etc.)		
Late pre-term status	Gestational age calculation (in weeks): 40+(b_date-p2)/7. (b_date=infant's birth date; p2=due date).	Neonatal questionnaire[d]	Dichotomous variable: yes (late preterm: 35 – 37 weeks gestation), or no
Postpartum factors			
Professional breastfeeding support (if needed)	a. "Did you have any of the following problems breastfeeding your baby during your first 2 weeks of breastfeeding?" 18 categories, one of which is: "I had no problems." b. "Did you get any help with these problems from a health professional, a lactation consultant, or a breastfeeding support group?" (yes/no)	Neonatal questionnaire[d]	Dichotomous variable to indicate professional breastfeeding support: "I had no problems" or "yes, mother got help with problems" is one category, and a response indicating a problem for which mother did not get help is the other category.

Work	"Did you work for pay any time during the past 4 weeks?" (yes/no)	2-month questionnaire[e]	Same as IFPS II.
Child care arrangement	"Which of the following circumstances describe your situation during the past 4 weeks? (If you have stopped breastfeeding or stopped working for pay, please answer for the time you were breastfeeding and working. If you have worked for less than 4 weeks, please answer for the time you have been working.)" Response categories: 1: I keep my baby with me while I work and breastfeed during my work day 2: I go to my baby and breastfeed him or her during my work day 3: My baby is brought to me to breastfeed during my work day 4: I pump milk during my work day and save it for my baby to drink later 5: I pump milk during my work day, but I do not save it for my baby to drink later 6: I neither pump milk nor breastfeed during my work day	2-month questionnaire[e]	Dichotomous variable: mother and infant were not separated (including mothers who did not work); or, mother and infant were separated.
Infant age when returned to work	"How old was your baby when you began working after your delivery? (If you are not sure, give your best estimate.)" Answer in months and weeks.	3-month questionnaire[f]	Continuous to 9 weeks (corresponding to exposure); 9 or more weeks is a separate, single category.
Work environment	"Have you had any of the following experiences during the past 4 weeks?" Responses: • A coworker made negative comments or complained to me about breastfeeding • My employer or my supervisor made	3-month questionnaire[f]	Assigned one point to each response and created a variable that is the sum of those points. This is a continuous variable (range: 0 – 8) that equally weights these issues. Mothers who did not report working at two months were assigned 0. Dichotomized for effect measure modification testing; categories: 0 and greater than 0.

	negative comments or complained to me about breastfeeding • It was hard for me to arrange break time for breastfeeding or pumping milk • It was hard for me to find a place to breastfeed or pump milk • It was hard for me to arrange a place to store pumped breast milk • It was hard for me to carry the equipment I needed to pump milk at work • I felt worried about keeping my job because of breastfeeding • I felt worried about continuing to breastfeed because of my job I felt embarrassed among coworkers, my supervisor, or my employer because of breastfeeding		
Workplace support	"In your opinion, how supportive of breastfeeding is your place of employment?" (3-month questionnaire); four categories: 1: Not at all supportive 2: Not too supportive 3: Somewhat supportive 4: Very supportive	3-month questionnaire[f]	Dichotomous variable: supportive (categories 3 and 4) and unsupportive (categories 1 and 2) workplaces. Mothers who did not report working at two months were put in the supportive group.

[a]NICU stay (extended infant stay in NICU) was identified to be part of the minimally sufficient adjustment set but is not included in this table. NICU stay is controlled for by the parent study exclusion of infants who spent more than three days in the NICU.
[b]Demographic information was collected routinely from questionnaires sent to panel members; a separate demographic questionnaire was sent to mothers living in the home of a panel member.
[c]Completed during third trimester

[d]Aims 1 and 1a: Median infant age when questionnaire was completed=4.3 weeks; range: 0.2 – 21.9; less than 10% completed it when infant was 8 weeks or older. Aims 2 and 2a: Median infant age when questionnaire was completed=4.7 weeks; range: 0.9 – 21.9; less than 10% completed it when infant was more than 7.6 weeks.

[e]Aims 1 and 1a: Median infant age when questionnaire was completed=9.0 weeks; range: 4.0 – 29.7; less than 10% completed it when infant was 13 weeks or older. Aims 2 and 2a: Median infant age when questionnaire was completed=9.7 weeks; range: 4.0 – 29.7; less than 10% completed it when infant was more than 12.7 weeks.

[f]These variables were measured after the exposure; however, we restrict "infant age when returned to work" to those returning in less than 9 weeks, and we applied workplace environment and support conditions only to those working at Month 2 and assumed that those conditions were true at that time. For the Month 3 questionnaire, the median infant age when questionnaire was completed=12.9 weeks; range: 10.9 – 29.6; less than 10% completed it when infant was 16 weeks or older (Aims 2 and 2a: 15.6 weeks or older).

Data Analysis

I performed all statistical analyses in SAS (version 9.4, Cary, NC, USA). About 20% of observations were missing values for more than one covariate. I used multiple imputation with 100 replications to address missing values, with confounders, potential effect measure modifiers, and selection factors (described below). I used the imputed dataset for all subsequent analyses except the Kaplan-Meier curves. I created inverse-probability (IP) of exposure weights to control confounding from the large groups of covariates (Cole & Hernán 2008). Figures 4 -7 show that the IP weights nearly equalized the covariate distributions between the exposed and unexposed women. I also stratified all analyses by work status. Women were considered to be working if they answered: "Did you work for pay any time during the past 4 weeks?" on the month 2 survey (answer: yes/no; CDC 2014) affirmatively. In addition, I tested for effect measure modification by obesity, income, work environment (among working women) and workplace support (among working women) for all analyses, and additionally by breastfeeding and exclusive breastfeeding intentions (alignment with recommended durations) for Aims 2 and 2a.

Figure 4: Weighted covariate distributions for the study population, Aim 1.

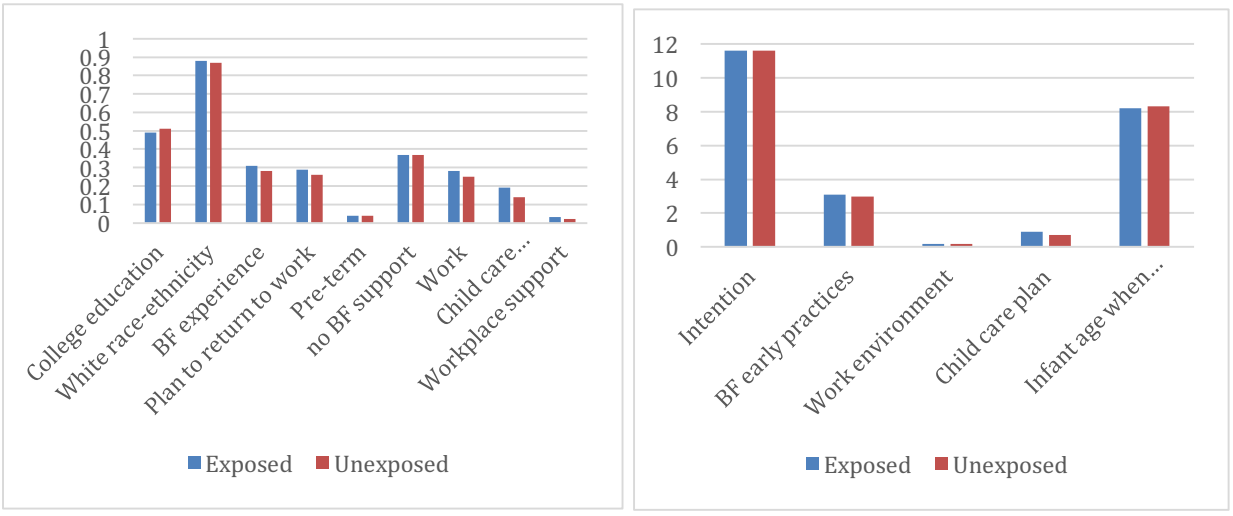


Figure 5: Weighted covariate distributions for the study population, Aim 1a.

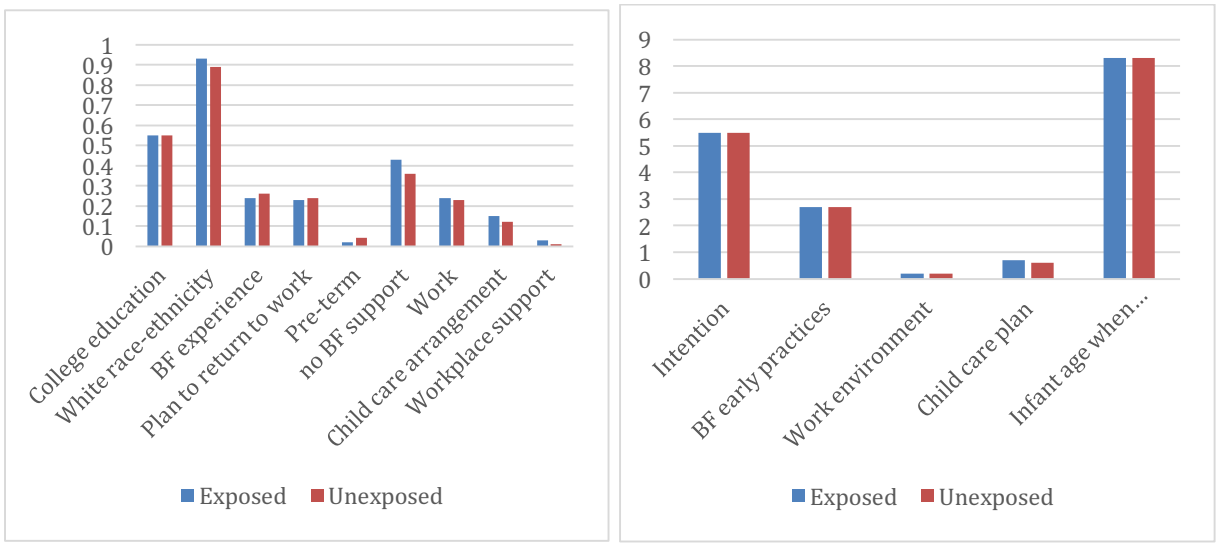


Figure 6: Weighted covariate distributions for the study population, Aim 2.

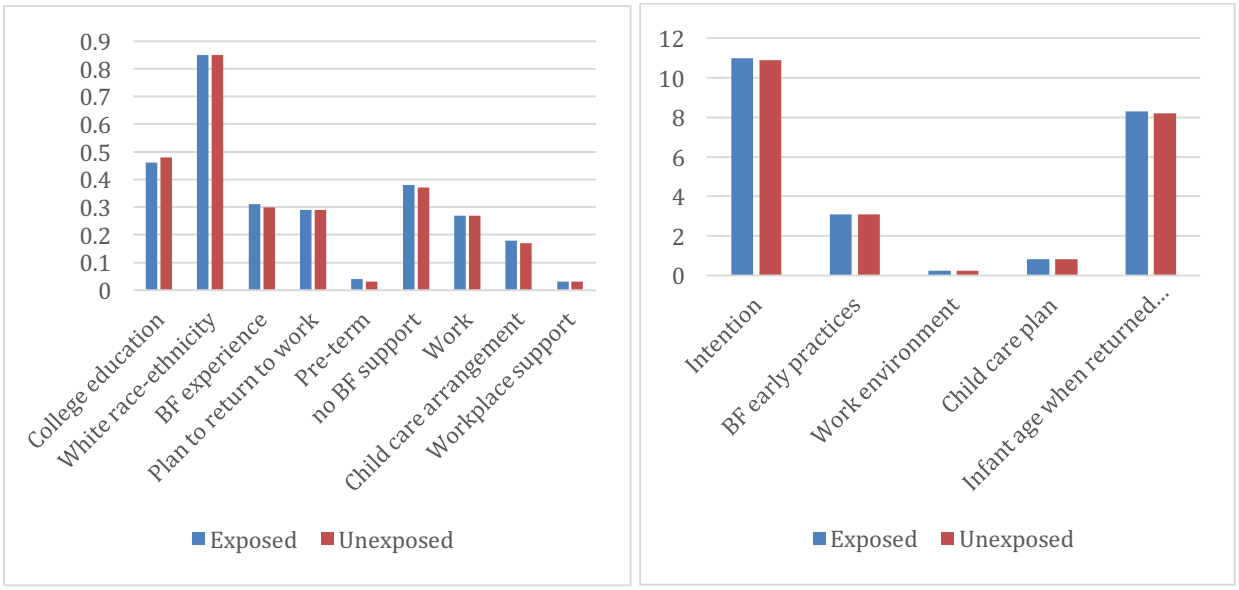
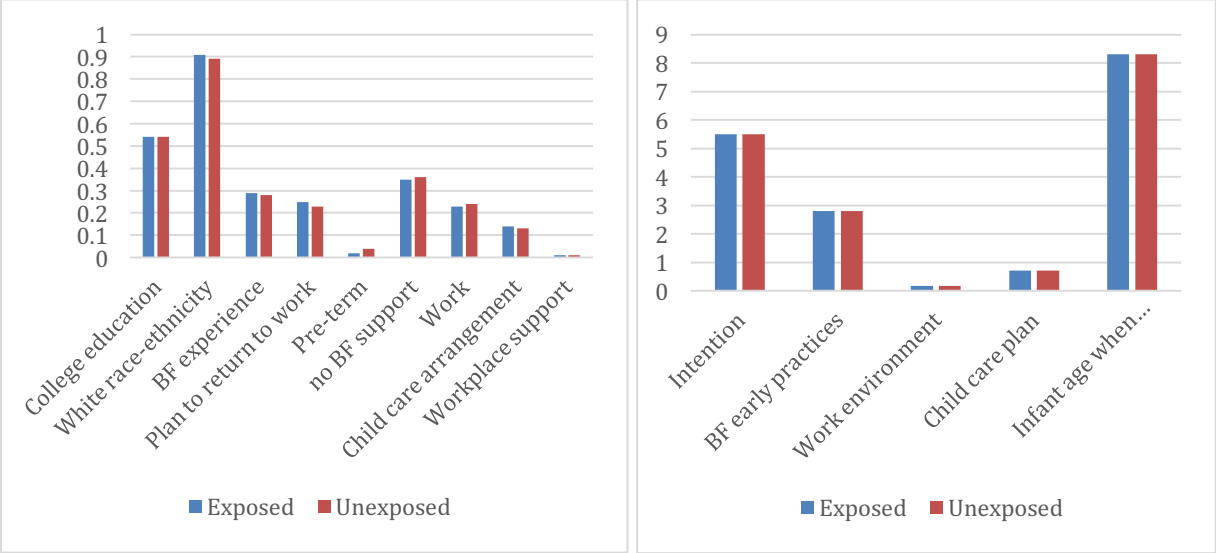


Figure 7: Weighted covariate distributions for the study population, Aim 2a.



These studies began at Month 2 because that is when the exposure was measured. I created IP of selection weights to address potential selection bias caused by women stopping BMF and exclusive BMF before these studies began, following methods reported by Bengtson *et al.* (2014). I considered factors associated with BMF and exclusive BMF at month 2 and then estimated the weights as the inverse probability of BMF (and exclusive BMF, separately), with these predictors for BMF (Aims 1 and 2): maternal age, college degree, experience of breastfeeding-related pain in the first two weeks, marital status, and plans to return to work within the first nine weeks. The selection weights for exclusive BMF for Aim 1a included all of the predictors for BMF except maternal age because it was not statistically significant at a=0.05, and the selection weights for exclusive BMF for Aim 2a included the same predictors except for breastfeeding-related pain in the first two weeks. I stabilized all of the selection weights by the marginal probabilities of reporting BMF or exclusive BMF at month 2. That reduced the weights

at the extremes, i.e., exposed women with a low probability of being exposed, and the converse (Xu *et al.* 2010).

Aims 1 and 1a: I fitted Cox proportional hazards regression models for BMF cessation (assessed at months 2 – 12) and for exclusive BMF cessation (assessed at months 2 – 6). I estimated hazard ratios for both BMF cessation and exclusive BMF cessation by pumping status. I also computed crude Kaplan-Meier curves with the unimputed dataset to illustrate the probabilities of BMF and exclusive BMF for the exposure groups over time. Since about 20% of observations were lost to follow-up, I created and applied time-varying IP drop-out weights. Those weights addressed possible selection bias due to loss to follow-up (Buchanan *et al.* 2014).

Aims 2 and 2a: I fitted weighted log-binomial models and estimated risk ratios for achieving BMF (Aim 2) and exclusive BMF (Aim 2a) intentions by pumping status.

Supplemental Analyses

I also calculated crude risks and rates for BME and exclusive BMF cessation, and estimated the weighted rate and risk ratios, risk difference and number needed to treat (Appendix A). These are other ways of thinking about the effect estimates, but are not part of my main analyses.

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CHAPTER 4: RESULTS

Section 4.1 Paper 1: Early, regular breast milk pumping may lead to early breast milk feeding cessation

Introduction

Breastfeeding has numerous benefits for maternal and child health (Grummer-Strawn & Rollins 2015) and society (Department of Health and Human Services (DHHS) 2011). Exclusive breastfeeding is recommended for six months and continued breastfeeding for one (American Academy of Pediatrics (AAP) 2012) or two years and beyond (World Health Organization (WHO) 2016). However, as recently as 2013, only 22% of infants born in the U.S. were exclusively breastfed for six months, and 31% were still breastfed at 12 months (Centers for Disease Control and Prevention (CDC) 2016). In 2015, nearly 55% of all mothers with a child under one year of age were working in the U.S. (Bureau of Labor Statistics (BLS) 2016). The timing of most women's return to work after birth overlaps with the recommended timeframe for breastfeeding; nearly half of working mothers returned to work within eight weeks of taking parental leave and 22% returned within two weeks (Klerman *et al*. 2014). Employed mothers have lower initiation rates and shorter durations of breastfeeding than those who are unemployed (DHHS 2011).

One way for women to continue breast milk feeding (BMF; including feeding at breast and feeding expressed breast milk) while working is to pump breast milk when separated from their infants (DHHS 2011). The prevalence of breast milk pumping is increasing (Johns *et al*. 2013), but its effect on duration among mothers returning to work in the early postpartum period is unknown. Pumping may enable women to continue BMF longer than if they had not pumped (Rasmussen & Geraghty 2011; Meehan *et al*. 2008), and current policies encourage pumping as a way to extend BMF duration (AAP 2013), but there is mixed evidence for an association of pumping with BMF duration (Johns *et al*. 2013). For example, in one observational study, low-income mothers who were given a breast pump requested formula four months after mothers who did not receive a pump (Meehan *et al*. 2008). In another observational study, however, mothers who pumped for non-elective reasons (including employment) had shorter BMF durations than those who pumped electively (Felice *et al.* 2016).

The purpose of this study was to estimate the effect of early (defined as infant age less than nine weeks), regular breast milk pumping on time to BMF and exclusive BMF cessation, for working and non-working women in the U.S. A better understanding of the relationship between early, regular pumping and BMF durations is critical to ascertain if workplace policies that support breast pumping actually have the intended consequence of extending the duration of BMF.

Methods

This is a secondary analysis of data from the Infant Feeding Practices Study II (IFPS II), a sample of pregnant women throughout the U.S., with follow-up during the first year of life. We used the de-identified, publicly available dataset, which was exempted from review by the Institutional Review Board of the University of North Carolina, Chapel Hill. The IFPS II was

conducted by the U.S. Centers for Disease Control and Prevention, the U.S. Food and Drug Administration, and other partners. Its methods are reported in detail elsewhere (Fein *et al.* 2008) and briefly summarized here.

Study population and data collection: The original study cohort comprised 3033 women who were aged 18 years or older in their third trimester and who delivered a live, singleton infant weighing 5 lb. or more at 35 weeks or more gestation, spent three or fewer days in the neonatal intensive care unit, and completed the neonatal survey (CDC 2012). Those women were members of, or living in the household of a member of, a consumer opinion panel. They completed a prenatal questionnaire at the time of enrollment, reporting information pertaining to prenatal care, maternal diet and postnatal plans for infant care and feeding, and then a telephone survey to report birth-related data, after which investigators confirmed eligibility. Women completed subsequent questionnaires monthly during months 2 – 7 and then every seven weeks until the twelfth month, providing information about child care, employment, infant feeding practices, sleep, maternal depression and infant health.

From the original study cohort (n=3033), we selected women who reported BMF on the month 2 questionnaire (n=1624), when the exposure (regular pumping) was measured (first analysis). For the second analysis, we selected women exclusively BMF at the time they completed the month 2 questionnaire (n=971) from the original study cohort (n=3033). Both BMF and exclusive BMF were determined by responses to questions about food consumed in the past seven days. If her infant consumed only breast milk, then a woman was considered to be exclusively BMF (CDC 2012).

Exposure assessment: The exposure for this study is "regular pumping," (including expressing breast milk in any way but not further defined on the questionnaire) that began when the infant

was less than nine weeks of age. Mothers responded to: "Are you now pumping milk on a regular schedule?" (answer: yes or no), followed by "How old was your baby when you first began pumping on a regular schedule?" (answer: number of days or weeks) on the 2-month questionnaire (CDC 2014). Less than 10% of questionnaires intended to be completed at month 2 (~8.6 weeks) were completed at 13 or more weeks after birth. All mothers who were not regularly pumping or not pumping at all were considered unexposed.

Outcome assessment: Although there is a growing body of research that distinguishes between feeding at breast and expressing breast milk for feeding (e.g., Felice *et al*. 2016), the IFPS II did not collect those data. Therefore, "BMF" in this study encompasses both practices. The main outcomes of interest were time to cessation of BMF (including exclusive and partial) and exclusive BMF. Women who continued BMF for at least the recommended duration were censored at the time of reaching the recommended duration (six months for exclusive BMF and 12 months for BMF; AAP 2012). Each monthly questionnaire contained a module for mothers to complete when they had stopped all breastfeeding and pumping. Respondents indicated infant age when the mother stopped breastfeeding and pumping milk (not necessarily when the infant stopped receiving breast milk). Thus, BMF duration for this analysis is a measure of the mother's practice. CDC imputed missing values for BMF duration (approximately 6% of original study population) (CDC 2012), which we used in our analysis. If a mother dropped out of the study, then she was censored and her BMF duration was recorded as her infant's age at the time of the last completed survey.

Exclusive BMF was measured on each monthly questionnaire through a series of questions about food consumption (CDC 2012). We used the IFPS II dataset variable for exclusive BMF duration that estimates the mid-point of infant age on the last questionnaire on

which the mother indicated exclusive BMF and on the first questionnaire that indicated she was not exclusively BMF. If a mother dropped out of the study, then she was censored and her exclusive BMF duration was recorded as her infant's age at the time of the last completed survey.

Analysis: To identify appropriate confounders, we created a directed acyclic graph (DAG; Greenland *et al.* 1999), informed by literature, expert consultation, and the Theory of Planned Behavior (Bai *et al.* 2011) (Dagitty v. 2.3). The variables we identified are described in detail in Table 1 and include: household income, maternal education, maternal race-ethnicity, previous breastfeeding experience, prenatal intention to breastfeed, child care plans, planning to return to work, breastfeeding initiation and early practices (index of equally weighted practices in the hospital or birth center that could affect breastfeeding: pacifier use, breastfeeding within the first hour, feeding other substances to infant, rooming in, breastfeeding support, referral for post-partum support, formula gift bag), professional breastfeeding support if needed, work, child care arrangement, infant age when mother returned to work, work environment (index of equally weighted unfavorable experiences: negative comments from coworker; negative comments from supervisor; difficulty arranging break time, place to pump, or place to store milk; difficulty carrying pumping equipment; worry about keeping job because of breastfeeding; worry about continuing to breastfeed because of job; embarrassed among coworkers or supervisor), and workplace support. We also tested for effect measure modification by obesity, income, work environment and workplace support. About 20% of respondents were missing values for more than one covariate.

We used multiple imputation with 100 replications to address the missing exposure and covariate values, using confounders, potential effect measure modifiers, and selection factors

(described below) as predictors. To control confounding from the large number of identified covariates, we created inverse-probability (IP) of exposure weights, using methods recommended by Cole and Hernán (2008). Under certain assumptions, the parameters produced by a weighted regression model can estimate the average causal effect of early, regular pumping in our study population (Cole & Hernán 2008).

To address potential selection bias we used two kinds of additional weights. This study began at month 2 because that was when the exposure (regular pumping) was reported, and, therefore, excludes women who stopped BMF before then. To address potential bias caused by that exclusion, we created and applied IP of selection weights using methods similar to those reported by Bengtson et al. (2016). To create those weights, we considered covariates associated with BMF and exclusive BMF at month 2 and then estimated the selection weights as the inverse probability of BMF (and exclusive BMF, separately), with these predictors in the weights equation for BMF: maternal age, college degree, experience of breastfeeding-related pain in the first two weeks, marital status, and plans to return to work within the first nine weeks. Selection weights for exclusive BMF included all of the predictors for BMF except maternal age because it was not statistically significant at a=0.05. We stabilized the weights by the marginal probability of BMF or exclusive BMF at month 2, which reduced the weights at the extremes, i.e., for exposed women with a low probability of exposure, and the converse (Xu *et al.* 2010). In addition, about 20% of observations were lost to follow-up. We created and applied time-varying IP drop-out weights to address possible selection bias due to loss to follow-up (Buchanan *et al.* 2014). All weights were created in the imputed dataset.

We used Cox proportional hazards regression models (SAS, Version 9.4, Cary, NC, USA) for the outcome assessed at months 2 – 12 (BMF) and months 2 – 6 (exclusive BMF) to

estimate the hazard ratio for BMF cessation according to pumping status in the imputed dataset. We then stratified the analyses by work status. Women were considered to be working if they answered: "Did you work for pay any time during the past 4 weeks?" on the month 2 survey (CDC 2014) affirmatively. Finally, we computed crude Kaplan-Meier curves with the unimputed dataset to illustrate the probability of BMF for the exposure groups over time.

Results

Most regular pumpers who were BMF at month 2 were married, white, not working, and had previous breastfeeding experience and a college degree (Table 2). In addition, most were working at the time of study enrollment (third trimester), had childcare plans for which they would be separated from their infants for feeding, and reported pumping so that someone else could feed their infants. Most non-regular/non-pumpers who were BMF had profiles similar to those of regular pumpers, except that most of the former were not working at the time of study enrollment and had childcare plans in which mother and infant were not separated for feeding. Sixty percent of non-regular/non-pumpers occasionally pumped, and most of them pumped so that someone else could feed their infants. Regular and non-regular/non-pumpers who were exclusively BMF had similar profiles to women in the BMF groups (Table 2).

The crude Kaplan-Meier curve for BMF diverged by pumping status at about 13 weeks, showing a lower probability of BMF for women who pumped regularly compared to women who did not (Figure 1). The crude curves stratified by work status also diverged at about 13 weeks, showing that women who neither worked nor pumped regularly had the highest probability of BMF, followed by women who worked but did not pump regularly, women who both worked and pumped regularly, and women who did not work but pumped regularly (Figure 8). The crude Kaplan-Meier curves for exclusive BMF show a divergence at about nine weeks, with regular pumpers having a lower probability of exclusively BMF at every subsequent time point

compared to non-regular/non-pumpers (Figure 9). The crude curves stratified by work status also diverged at about nine weeks, with regular pumpers who were not working having the lowest probability of exclusively BMF, while the other groups had cessation rates similar to one another.

In the first weighted Cox proportional hazards regression model, regular pumpers had an increased hazard of early BMF cessation (hazard ratio (HR)=1.62; 95% confidence interval (CI) 1.47 – 1.78; Table 3) compared to non-regular/non-pumpers. When stratified by working status, the estimated effect of regular pumping on time to BMF cessation was close to the null among working women (HR=0.90; 95% CI 0.75 – 1.07), but was two times higher among non-working women (HR=2.05; 95% CI 1.84 – 2.28). In the second weighted Cox proportional hazards regression model, regular pumpers had an increased hazard of early exclusive BMF cessation (HR=1.14; 95% CI 1.03 – 1.25; Table 3) compared to non-regular/non-pumpers. When stratified by working status, the estimated effect of regular pumping on time to exclusive BMF cessation was higher than non-regular/non-pumping among working women (HR=1.15; 95% CI 0.96 – 1.37), but the CI includes the null value. Similarly, among non-working regular pumpers, the estimated effect of regular pumping was close to the null, compared to non-regular/non-pumping (HR=1.10; 95% CI 0.98 – 1.22).

Of the four variables tested, only work environment ($p<0.05$) was a statistically significant effect measure modifier. Regular pumpers who had no unfavorable experiences at work had a greater hazard of BMF cessation than non-regular/non-pumpers (HR 1.32; 95% CI 1.06 – 1.65). For working women who regularly pumped and had unfavorable experiences at work, regular pumping appeared to be protective against exclusive BMF cessation, although the CI includes the null value (HR 0.82; 95% CI 0.61 – 1.10).

When we reviewed the characteristics of regular pumpers we found that 45% who BMF and did not work at month 2 had planned to return to work in the first year (Table 4). For those exclusively BMF, 33% who did not work at month 2 had planned to return to work in the first year, and nearly half (48%) had not planned to return to work in the first year. The main reasons why non-workers pumped regularly at month 2 included: for someone else to feed the baby (76% BMF and 82% exclusive BMF) and to have an emergency supply of breast milk (56% BMF and 68% exclusive BMF).

Table 2: Maternal and infant descriptive characteristics for 1624 U.S. women in the IFPS II, 2005-7.

	Any breast milk feeding at two months (N=1624)[a]		**Exclusive breast milk feeding at two months (N=971)[b]**	
	Regularly pumping[c] (n=347)	Not regularly pumping (n=1235)	Regularly pumping[c] (n=199)	Not regularly pumping (n=754)
	N(%) Mean (SD)	N(%) Mean (SD)	N(%) Mean (SD)	N(%) Mean (SD)
Age				
Maternal age at study enrollment[d]	29.6 (4.7)	29.7 (5.2)	29.6 (4.5)	29.7 (5.0)
Income				
Median household	$45,000 – $49,999	$40,000 - $44,999	$45,000 – $49,999	$40,000 - $44,999
Education				
College graduate or more	198 (57%)	538 (44%)	125 (63%)	366 (49%)
Some college or less	135 (39%)	644 (52%)	74 (37%)	367 (49%)
Missing	14 (4%)	53 (4%)	0	6 (1%)
Race/Ethnicity				
White, non-Hispanic	284 (82%)	1051 (85%)	164 (82%)	665 (88%)
Black, non-Hispanic	14 (4%)	36 (3%)	9 (5%)	15 (2%)
Hispanic	19 (6%)	72 (6%)	11 (6%)	32 (4%)
Other	20 (6%)	54 (4%)	8 (4%)	31 (4%)
Missing	10 (3%)	22 (2%)	7 (4%)	11 (1%)
Parity				
Other babies had	0.9 (1.0)	1.4 (1.3)	0.9 (1.0)	1.4 (1.2)
Missing	8 (2%)	16 (1%)	4 (2%)	7 (1%)
Marital status				
Married	281 (81%)	1023 (83%)	165 (83%)	670 (89%)
Single/Divorced/ Separated	50 (15%)	174 (13%)	26 (13%)	64 (9%)

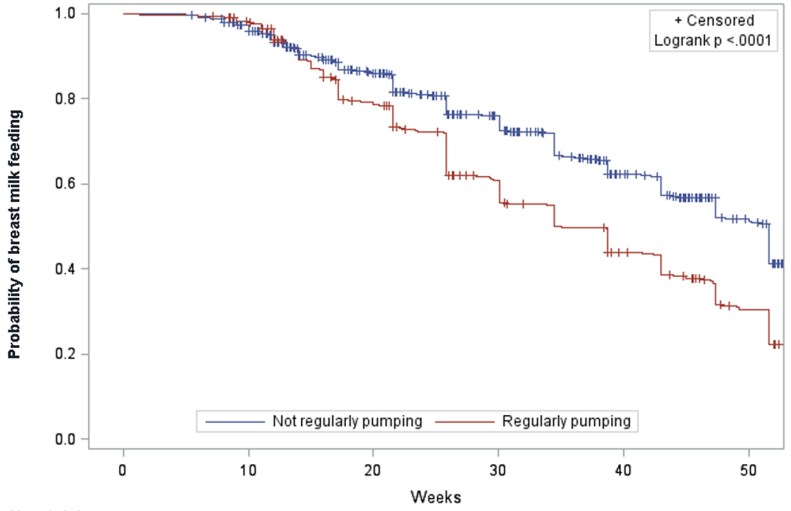
Missing	16 (5%)	48 (4%)	1 (1%)	5 (1%)
Previous breastfeeding experience				
Yes	186 (53%)	904 (74%)	103 (52%)	578 (77%)
No	149 (44%)	304 (24%)	88 (45%)	163 (22%)
Missing	12 (3%)	27 (2%)	8 (4%)	13 (2%)
Maternal BMI (pre-pregnancy)				
Underweight	11 (3%)	50 (4%)	7 (4%)	35 (5%)
Normal	169 (49%)	589 (48%)	102 (51%)	387 (51%)
Overweight	104 (30%)	305 (25%)	56 (28%)	178 (24%)
Obese	61 (17%)	276 (22%)	33 (17%)	146 (19%)
Missing	2 (1%)	15 (1%)	1 (1%)	8 (1%)
Working at time of study enrollment				
Yes	253 (73%)	531 (43%)	148 (74%)	299 (40%)
No	90 (26%)	687 (56%)	49 (25%)	445 (59%)
Missing	4 (1%)	17 (1%)	2 (1%)	10 (1%)
Prenatal intention to breastfeed[e]				
Months (median)	10.0	12.0	5-6	5-6
Missing	9 (3%)	99 (8%)	24 (12%)	78 (10%)
Child care plans				
Mother/infant together	97 (27%)	753 (61%)	56 (27%)	505 (67%)
Mother/infant separated	201 (58%)	331 (27%)	115 (58%)	153 (20%)
Combination/not sure	47 (14%)	143 (12%)	27 (14%)	89 (12%)
Missing	2 (1%)	8 (1%)	1 (1%)	7 (1%)
Planning to return to work				
Within 9 weeks	155 (45%)	316 (26%)	88 (44%)	154 (20%)
After 9 weeks but within first year	114 (33%)	296 (24%)	68 (34%)	175 (23%)
Not planning to return in first year	75 (22%)	612 (50%)	41 (21%)	416 (55%)
Missing	3 (1%)	11 (1%)	2 (1%)	9 (1%)
Breastfeeding initiation and early practices				
Mean score[f]	3.1 (1.4)	3.1 (1.5)	2.9 (1.4)	2.9 (1.4)
Missing	9 (3%)	36 (3%)	3 (2%)	25 (3%)
Late pre-term status				
Yes	18 (5%)	36 (3%)	9 (5%)	12 (2%)
No	329 (95%)	1199 (97%)	190 (95%)	742 (98%)
Breastfeeding problems				
No	41 (11%)	165 (13%)	25 (13%)	122 (16%)
Yes	304 (88%)	1061 (86%)	174 (87%)	632 (84%)
Got help	204 (59%)	582 (47%)	114 (57%)	299 (40%)
Did not get help	99 (29%)	479 (39%)	60 (30%)	330 (44%)
Missing	1 (0)	9 (1%)	0	3 (0)

Post-partum depression				
Average score	6.3 (4.2)	6.6 (4.5)	5.9 (4.1)	6.0 (4.2%)
Score ≥13[g]	29 (8%)	117 (9%)	14 (7%)	51 (7%)
Score <13	310 (89%)	1082 (88%)	179 (90%)	683 (91%)
Missing	8 (2%)	36 (3%)	6 (3%)	20 (3%)
Working[h]				
Yes	161 (46%)	251 (20%)	88 (44%)	130 (17%)
No	182 (52%)	920 (75%)	111 (56%)	590 (78%)
Missing	4 (1%)	64 (5%)	0	34 (5%)
Reasons for pumping in past two weeks (n= pumping)[i]	347 (100%)	741 (60%)	199 (100%)	468 (62%)
Engorgement	126 (36%)	318 (43%)	72 (36%)	190 (41%)
Sore nipples	13 (4%)	33 (4%)	11 (6%)	11 (0)
Increase milk supply	155 (45%)	202 (27%)	87 (44%)	99 (21%)
For someone else to feed baby	278 (80%)	456 (62%)	170 (85%)	313 (67%)
Does not want to breastfeed or infant cannot	140 (40%)	192 (26%)	71 (36%)	100 (21%)
To maintain supply when infant could not nurse (separation or infant illness)	127 (37%)	160 (22%)	66 (33%)	74 (16%)
To mix with food	20 (6%)	22 (3%)	2 (1%)	9 (2%)
To donate	4 (1%)	1 (0)	3 (2%)	0
To have an emergency supply	164 (47%)	293 (40%)	117 (59%)	221 (47%)
Missing	17 (1%)	4 (1%)	1 (1%)	9 (2%)
Child care arrangement				
Mother and infant are sometimes separated for feeding	138 (40%)	109 (10%)	75 (38%)	43 (6%)
Mother and infant are never separated for feeding	20 (6%)	126 (10%)	13 (7%)	83 (11%)
Missing	4 (1%)	64 (5%)	0	34 (5%)
Not working	182 (52%)	920 (75%)	111 (56%)	590 (78%)
Hostile work environment				
Mean score[f]	1.2 (1.6)	0.6 (1.3)	1.2 (1.7)	0.5 (1.1)
Missing	34 (21%)	50 (20%)	17 (19%)	20 (15%)
Not working	182 (52%)	920 (75%)	111 (56%)	590 (78%)
Infant age when mother returned to work				
<9 weeks	109 (31%)	155 (13%)	57 (29%)	83 (11%)
≥9 weeks	26 (7%)	61 (5%)	17 (9%)	31 (4%)
Missing	30 (9%)	99 (8%)	14 (7%)	50 (7%)
Not working	182 (52%)	920 (74%)	111 (56%)	590 (78%)
Workplace support				

Not at all supportive	5 (1%)	6 (0)	2 (1%)	2 (0)
Not too supportive	14 (4%)	13 (1%)	8 (4%)	3 (0)
Somewhat supportive	41 (12%)	39 (3%)	19 (10%)	18 (2%)
Very supportive	75 (22%)	152 (12%)	46 (23%)	91 (12%)
Missing	26 (7%)	41 (3%)	13 (7%)	50 (7%)
Not working	182 (52%)	920 (75%)	111 (56%)	590 (78%)
Breast milk feeding duration (weeks)	32.5 (15.5)	37.2 (16.4)	15.2 (6.3)	16.6 (6.9)

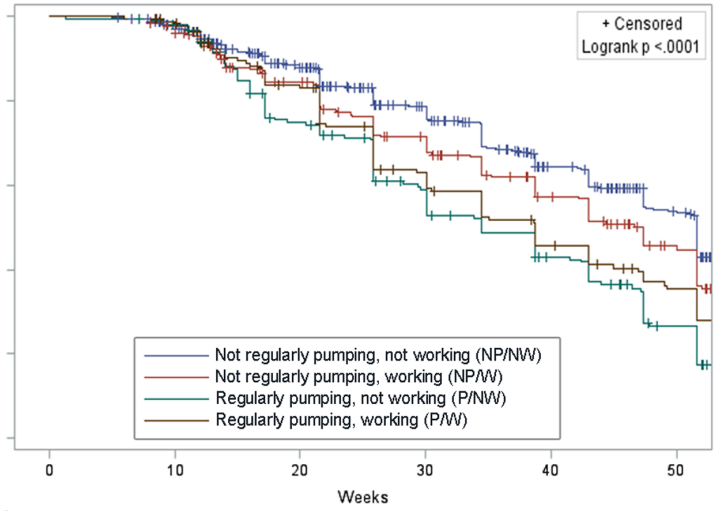
[a]Missing=6
[b]Missing=13; exclusive breastfeeding is a subset of any breastfeeding
[c]Missing=42
[d]Women enrolled during the third trimester.
[e]Measured in months for any breastfeeding and by month range for exclusive breastfeeding (median reported)
[f]Variable composition described in Table S.1.
[g]Referral for depression treatment is recommended for score of 13 or higher on the Edinburgh Postpartum Depression Screening tool.
[h]Worked sometime in past four weeks, from time completed Month 2 questionnaire
[i]This is the denominator (those who had pumped) for the list of reasons pumped. Respondents could choose more than one reason.

Figure 8: Kaplan-Meier curves for 1624 women in the U.S. IFPS II feeding breast milk to their infants, by pumping practice and work status, 2005-7.*



No. at risk						
Not regularly pumping	1235	1166	975	810	616	462
Regularly pumping	347	335	252	180	124	77

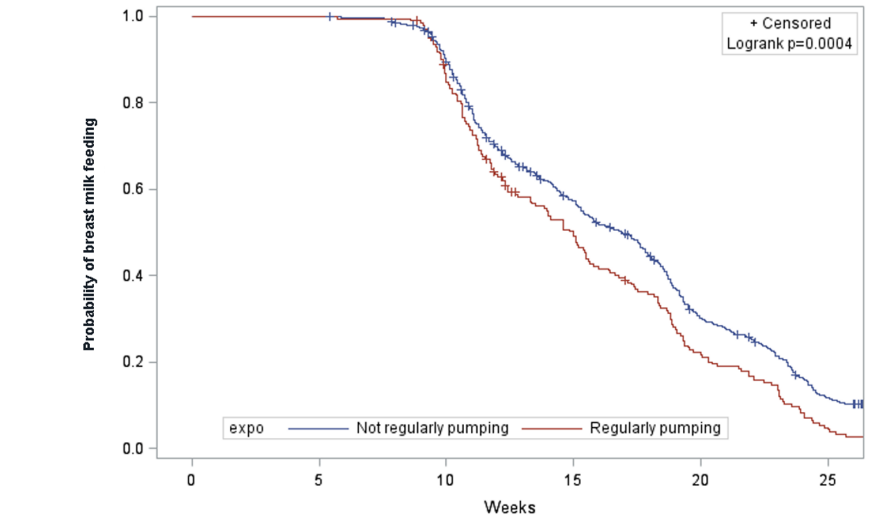
*Crude curves calculated from unimputed dataset; 42 observations missing (<3%)



No. at risk						
NP/NW	920	875	745	622	477	367
NP/W	251	238	192	155	114	78
P/NW	182	176	127	94	64	34
P/W	161	155	121	85	60	43

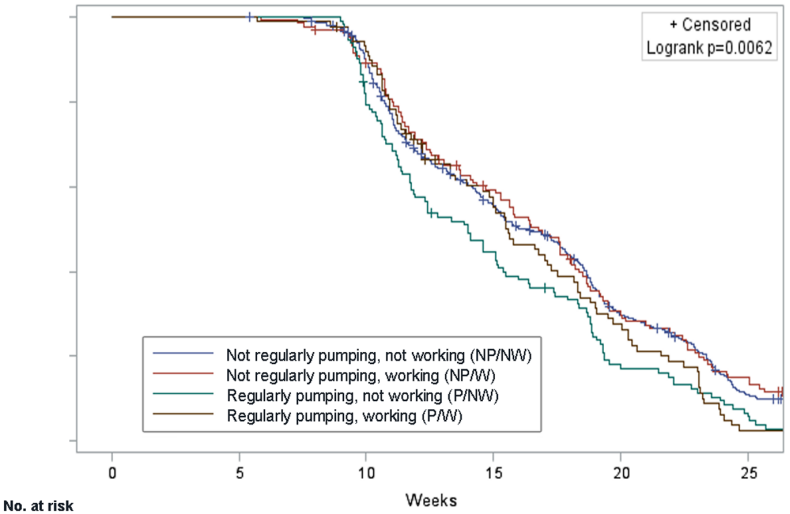
*Crude curves calculated from unimputed dataset; 110 observations missing (<7%)

Figure 9: Kaplan-Meier curves for 971 women in the U.S. IFPS II exclusively feeding breast milk to their infants, by pumping practice and work status, 2005-7.*



No. at risk						
Not regularly pumping	754	753	666	413	210	81
Regularly pumping	199	199	167	92	40	8

*Crude curves calculated from unimputed dataset; 18 observations missing (<2%)



No. at risk						
NP/NW	590	589	519	314	162	58
NP/W	130	130	114	73	36	18
P/NW	111	111	87	48	18	6
P/W	88	88	80	44	22	2

*Crude curves calculated from unimputed dataset; 52 observations missing (<6%)

Table 3: Hazard ratios for the effect of regularly pumping on time to stopping breast milk feeding for 1624 women in the IFPS II, 2005-2007.

	No. regularly pumping	No. not regularly pumping	Crude[a,b] (95% Confidence Interval)	Weighted[c] (95% Confidence Interval)
Breast milk feeding (n=1624)				
Overall[d]	347	1235	1.63 (1.49 – 1.78)	1.62 (1.47 – 1.78)
Work status[e]				
Working	161	251	1.17 (1.01 – 1.35)	0.90 (0.75 – 1.07)
Not working	182	920	2.02 (1.80 – 2.27)	2.05 (1.84 – 2.28)
Exclusive breast milk feeding (n=971)				
Overall[f]	199	754	1.31 (1.20 – 1.43)	1.14 (1.03 – 1.25)
Work status[g]				
Working	88	130	1.47 (1.27 – 1.70)	1.15 (0.96 – 1.37)
Not working	111	590	1.20 (1.06 – 1.36)	1.10 (0.98 – 1.22)

[a]BMF: weighted for selection (mean=0.98; range: 0.70 – 5.21) and loss to follow-up (mean=1.00; range: 0.33 – 2.79) in imputed dataset
[b]Exclusive BMF: weighted for selection (mean=1.00; range: 0.48 – 6.86) and loss to follow-up (mean=1.00; range: 0.09 – 5.41)
[c]Weighted with inverse-probability of exposure weights to control for household income, education, white race-ethnicity, prenatal breastfeeding intention, child care plan, plan to return to work within 9 weeks, early breastfeeding practices, accessing help for breastfeeding problems, infant age when mother returned to work, mother-infant sometimes separated for feeding, work, late pre-term status, work environment, and workplace support. Also weighted for selection and loss to follow-up in imputed dataset. BMF weights (mean=0.98; range: 0.24 – 8.98); Exclusive BMF weights: (mean=1.00; range: 0.21 – 14.82)
[d]Missing=42 (<3%)
[e]Reported on 2-month questionnaire; missing=68 (<5%)
[f]Missing=18 (<2%)
[g]Reported on 2-month questionnaire; missing=34 (<4%)

Table 4: Maternal and infant descriptive characteristics for 347 U.S. women, by work status, in the IFPS II, 2005-7.

	Any breast milk feeding at two months and regularly pumping (N=347)		Exclusive breast milk feeding at two months and regularly pumping (N=199)[a]	
	Working[b] (n=161)	Not working (n=182)	Working[c] (n=88)	Not working (n=111)
	N(%) Mean (SD)	N(%) Mean (SD)	N(%) Mean (SD)	N(%) Mean (SD)
Age				
Maternal age at study enrollment[d]	29.2 (4.7)	29.9 (4.6)	29.6 (4.6)	29.6 (4.5)
Income				
Median household	$50,000 – $59,999	$50,000 – $59,999	$50,000 – $59,999	$60,000 - $74,999
Education				
College graduate or more	94 (58%)	102 (56%)	54 (61%)	71 (64%)
Some college or less	61 (38%)	73 (40%)	32 (36%)	35 (32%)
Missing	6 (4%)	7 (4%)	2 (2%)	5 (5%)
Race/Ethnicity				
White, non-Hispanic	132 (82%)	149 (82%)	72 (82%)	92 (83%)
Black, non-Hispanic	6 (4%)	8 (4%)	3 (3%)	6 (5%)
Hispanic	8 (5%)	11 (6%)	6 (7%)	5 (5%)
Other	11 (7%)	8 (4%)	4 (5%)	4 (4%)
Missing	4 (2%)	6 (3%)	3 (3%)	4 (4%)
Parity				
Other live births	0.9 (1.0)	0.8 (1.0)	1.0 (0.9)	0.8 (1.0)
Missing	8 (2%)	3 (2%)	2 (2%)	2 (2%)
Marital status				
Married	130 (81%)	150 (82%)	71 (81%)	94 (85%)
Single/Divorced/ Separated	25 (16%)	23 (13%)	15 (17%)	11 (10%)
Missing	6 (4%)	9 (5%)	2 (2%)	6 (5%)
Previous breastfeeding experience				
Yes	95 (59%)	88 (48%)	52 (59%)	51 (46%)
No	61 (38%)	88 (48%)	33 (38%)	55 (50%)
Missing	5 (3%)	6 (3%)	3 (3%)	5 (5%)
Prenatal intention to breastfeed[e]				
Months (median)	9.9 (4.6)	10.0 (4.6)	5-6	5-6
Missing	4 (2%)	5 (3%)	14 (16%)	10 (9%)
Planning to return to work				
Within 9 weeks	120 (75%)	34 (19%)	68 (77%)	20 (18%)
After 9 weeks but within first year	32 (20%)	81 (45%)	15 (17%)	37 (33%)

Not planning to return in first year	8 (5%)	65 (36%)	4 (5%)	53 (48%)
Missing	1 (1%)	2 (1%)	1 (1%)	1 (1%)
Breastfeeding initiation and early practices				
Mean score[f]	3.1 (1.5)	3.1 (1.4)	2.9 (1.5)	2.8 (1.3)
Missing	1 (1%)	8 (4%)	1 (1%)	2 (2%)
Breastfeeding problems				
No	25 (16%)	15 (8%)	15 (17%)	10 (9%)
Yes	136 (84%)	165 (91%)	73 (83%)	101 (91%)
Got help	85 (53%)	116 (64%)	45 (51%)	75 (68%)
Did not get help	51 (32%)	48 (26%)	28 (32%)	26 (23%)
Missing	0	3 (2%)	0	0
Post-partum depression				
Average score	6.4 (3.7)	6.3 (4.7)	6.2 (3.8)	5.7 (4.2)
Score $\geq$13[g]	9 (6%)	20 (11%)	8 (9%)	6 (5%)
Score <13	150 (93%)	157 (86%)	78 (89%)	101 (91%)
Missing	2 (1%)	5 (3%)	2 (2%)	4 (4%)
Reasons for pumping in past two weeks[h]				
Engorgement	52 (32%)	72 (40%)	28 (32%)	44 (40%)
Sore nipples	5 (3%)	8 (4%)	4 (5%)	7 (6%)
Increase milk supply	69 (43%)	84 (46%)	36 (41%)	51 (46%)
For someone else to feed baby	137 (85%)	138 (76%)	79 (90%)	91 (82%)
Does not want to breastfeed or infant cannot	55 (34%)	84 (46%)	28 (32%)	43 (39%)
To maintain supply when infant could not nurse (separation or infant illness)	75 (47%)	50 (27%)	38 (43%)	28 (25%)
To mix with food	9 (6%)	11 (6%)	1 (1%)	1 (1%)
To donate	3 (2%)	1 (1%)	2 (2%)	1 (1%)
To have an emergency supply	60 (37%)	102 (56%)	42 (48%)	75 (68%)
Missing	0	4 (2%)	1 (1%)	9 (8%)
Breast milk feeding duration (weeks)	35.6 (15.7)	32.7 (15.4)	16.1 (5.3)	15.3 (6.2)
Missing	28 (17%)	31 (17%)	6 (7%)	3 (3%)

[a]Exclusive breastfeeding is a subset of any breastfeeding.
[b]Worked for pay sometime in past four weeks, from time completed Month 2 questionnaire; Missing=4
[c]Worked for pay sometime in past four weeks, from time completed Month 2 questionnaire; Missing=0
[d]Women enrolled during the third trimester.
[e]Measured in months for any breastfeeding and by month range for exclusive breastfeeding (median reported)
[f]Variable composition described in Table S.1.
[g]Referral for depression treatment is recommended for score of 13 or higher on the Edinburgh Postpartum Depression Screening tool.
[h]Respondents could choose more than one reason.

Discussion

This study estimated the effect of regular breast milk pumping in the early postpartum period on time to BMF and exclusive BMF cessation, up to the recommended durations (12 months and six months, respectively), among working and non-working women in the U.S. We found that regular pumpers were more than 60% more likely to stop BMF, and nearly 15% more likely to stop exclusive BMF, than non-regular/non-pumpers, within the recommended time frames. Work status modified the association only for women who BMF. Among working women who BMF, regular pumping had a nearly null estimated effect; however, non-working women who regularly pumped were more than twice as likely to stop BMF as non-regular/non-pumpers. Among working women who exclusively BMF, our findings suggested an elevated hazard for regular pumping compared to non-regular/not pumping, although the CI included the null. There was a similar estimation for non-working women who exclusively BMF.

These results suggest that regular pumpers in the early postpartum period, including those who are not working, may be more likely to stop BMF than their non-regular/non-pumping counterparts, and may need specialized support in order to BMF for the recommended duration. Further, regular pumping, as opposed to non-regular/not pumping, may not affect working women's BMF and exclusive BMF durations, despite policy intentions (AAP 2013) and national goals to increase BMF duration (DHHS 2017). This finding suggests that workplace protections of BMF that focus solely on pumping may not be effective in improving BMF and exclusive BMF practices among working women.

One explanation for the observed association between pumping and early cessation of BMF could be that women who pumped to build a supply of expressed milk planned to use that supply to continue BMF after they returned to work, but, perhaps, intended to pump less often

than their infants' feeding patterns, or not at all, at work. Not removing milk at regular intervals during the workday would eventually decrease supply (Mannel & Walker 2013), which could lead to BMF cessation. Many regular pumpers who were not working at month 2 had planned to return to work within the first year. Most regular pumpers in this study cited reasons for pumping that could be related to employment (Geraghty *et al.* 2012), although that was not specified.

The fact that regular pumping was not associated with BMF and exclusive BMF cessation among working women in our study was somewhat surprising, and may represent the statistical equalizing of two different strategies for BMF at month 2 in this population. The first strategy, mentioned above in the context of women who were not working at month 2, could also apply to women working at month 2, with the same consequence through the aforementioned biological mechanism. The second strategy, pumping at work, could lead to early cessation for some but not others, due to: a biological mechanism through which repeated ineffective (Mannel & Walker 2013) or infrequent milk removal could decrease supply (Baker & Lamb 2013); a reluctance to pump due to the psychological and logistical burdens of carrying pumping supplies and equipment, and of negotiating time and space for pumping during the workday, as well as milk storage; or unknown factors. Our findings suggested a potentially protective effect of regular pumping for women working in unfavorable environments, although the estimate was not statistically significant. If other studies find such an effect, it could reflect determination to persist despite unfavorable conditions, or perhaps circumstances in which increased visibility due to regular pumping was associated with more unfavorable experiences.

Our findings are particularly salient for the U.S., which lacks basic maternity protections such as paid leave and affordable, high-quality child care for all families. However, the U.S. supports breast milk pumping as a way for mothers to continue BMF when they are separated

from their infants due to work (AAP 2013). These data were collected before ACA protections for breast milk pumping in the workplace. Nonetheless, this study provides some indication of expectations for the effect of regular pumping on BMF duration. Our findings align with the results of a study using similar data (Felice *et al.* 2016). Another study with similar data reported that women who pumped at work had longer BMF durations than those who neither pumped nor fed at breast during work time, but shorter BMF durations than women who only fed at breast, or both pumped and fed at breast during work time (Fein *et al.* 2008). That study indicated some benefit for pumpers, although neither the regularity nor frequency of pumping was considered (Fein *et al.* 2008). Prospective studies using data collected after the ACA was enacted would provide a useful comparison to understand how its pumping protections may have changed the experiences of, as well as the BMF intensity (exclusive vs. any) and durations, for working mothers. In particular, further research among women from various income levels and occupations, and who combine working with BMF using different strategies including minimizing maternal-infant separation, as some have recommended (Fein *et al.* 2008; Academy of Breastfeeding Medicine 2013), would be particularly useful.

Strengths of this study included the use of IP weights to control confounding, which improved model parsimony, and selection and drop-out weights to address selection bias. There is still selection bias related to membership on consumer panels and meeting participation criteria for the parent study, which prevent generalization of these results to the U.S. maternity population. The parent study population has been reported to be better off than the general maternity population in the U.S. (CDC 2012). Thus, our results may be a conservative estimate of the effect of regular pumping on time to BMF and exclusive BMF cessation in the general population, if the observed effect could be stronger for those with fewer resources.

There may also be confounding by indication (a type of selection bias), meaning that women may not be included in this study because they decided not to BMF because they knew that they would be returning to work early and could not combine BMF with working. We believe that the statistical models are well specified because we consulted literature and subject matter experts during the creation of the DAG; however, "regular pumping" was not defined on the questionnaire and may not have been interpreted the same way by all respondents.

In addition, some questionnaires were not completed at the intended time, resulting in possible misclassification or recall bias. Approximately 10% of women completed month 2 questionnaires more than 13 weeks after childbirth. The variation in time of questionnaire completion could have caused limited misclassification of work status. Finally, exclusive BMF measurement assessed behavior during the past seven days; it is assumed that this practice was constant for the remaining days of the month. This is a common but imperfect way to measure exclusive BMF practice.

Section 4.2 Paper 2: Estimated effects of breast milk pumping on achievement of breastfeeding intentions in a sample of women in the U.S.

Introduction

The benefits of breastfeeding, for maternal and child health and for society at large, are well documented (Grummer-Strawn & Rollins 2015; Department of Health and Human Services (DHHS) 2011). However, despite recommendations for exclusive breastfeeding for six months and continued breastfeeding for one (American Academy of Pediatrics (AAP) 2012) or two years and beyond (World Health Organization 2011), most infants in the U.S. are not breastfed (Centers for Disease Control (CDC) 2016). Numerous factors have been associated with suboptimal breastfeeding, including non-white race, low birth weight, young maternal age, poor mental or emotional health, lack of knowledge about breastfeeding, embarrassment, lactation problems, maternal employment, social norms, poor social support, health care practices that separate mother and infant after birth, child care provider practices, and no intention to breastfeed (DHHS 2011; Jones *et al.* 2011; Donath *et al.* 2003; DHHS 2009; Cohen *et al.* 1995).

Breastfeeding intentions stated during the prenatal period are strong predictors of breastfeeding outcomes (Bonuck *et al.* 2005; Duckett *et al.* 1998). The Theory of Planned Behavior (TPB), which posits that intention precedes action, has underpinned a few breastfeeding studies (e.g., Duckett *et al.* 1998; Bai *et al.* 2010). TPB's premise is that perceived behavioral control (based on past experience and anticipated obstacles), behavioral attitude (favorable to unfavorable) and subjective norm (beliefs of key influencers combined with the importance of their beliefs to the subject) influence behavior by affecting one's intention to engage in the behavior (Wambach 1997; Ajzen 1991). Bai et al. (2010) found that these three main influencers of intention accounted for more than half of the variability in mothers'

intentions to exclusively breastfeed and also found a strong, positive correlation between intention and exclusive breastfeeding duration.

Although the prevalence of breast milk pumping is increasing (Johns *et al.* 2013), its effect on mothers' meeting their intentions regarding breast milk feeding (BMF), including feeding expressed breast milk and feeding at the breast, is unknown. Mothers may think that pumping will allow them to continue BMF longer than they could without pumping (Rasmussen & Geraghty 2011). However, in a study where 60% of mothers did not breastfeed for as long as they had wanted, Odom *et al.* (2013) found an association with mothers' concerns about the effort that pumping required. There is mixed evidence about the association of pumping with breastfeeding duration among healthy, term infants. In their literature review, Johns *et al.* (2013) found many descriptive studies, and their efforts to synthesize analytic findings were complicated by imprecise definitions of breastfeeding.

With increasing prevalence (Johns *et al.* 2013) and policy support for pumping among working women (AAP 2013), it is important to understand the relationship between pumping and achievement of BMF intentions. The purpose of this study was to estimate the effect of early, regular breast milk pumping on achievement of BMF and exclusive BMF intentions among a sample of working and non-working women in the U.S.

Methods

This is a secondary analysis of data from the Infant Feeding Practices Study II (IFPS II), conducted by the U.S. Centers for Disease Control and Prevention, the U.S. Food and Drug Administration, and other federal partners. Its methods are reported in detail elsewhere (Fein *et al.* 2008). We used the de-identified, publicly available dataset, and this study was exempted from review by the Institutional Review Board of the University of North Carolina, Chapel Hill.

Study population and data collection: The original study cohort included 3033 women who were 18 years or older in their third trimester, who delivered a live, singleton infant weighing 5 lb. or more (~2268g) at 35 weeks or more gestation, spent three or fewer days in the neonatal intensive care unit, and completed the neonatal survey (CDC 2012). Those women participated in a consumer opinion panel or were living in the household of a participant. Women completed a prenatal questionnaire at the time of enrollment and then a telephone survey to report birth-related data, at which time their eligibility was confirmed. They completed subsequent questionnaires monthly during months 2 – 7 and then every seven weeks until the twelfth month, providing information about infant feeding practices, infant health, child care, employment, sleep, and maternal depression.

For the analysis of BMF, we restricted the original study cohort (n=3033) to women who 1) reported an intention to BMF on the prenatal questionnaire and 2) reported BMF on the 2-month survey, when the exposure (regular pumping) was measured (n=1512). Similarly, for the analysis of exclusive BMF, we restricted the original study population (n=3033) to women who 1) made a prenatal intention to exclusively BMF and 2) reported exclusively BMF on the 2-month survey, when the exposure (regular pumping) was measured (n=867). A woman was considered to be exclusively BMF if her infant consumed only breast milk (CDC 2012).

Exposure assessment: The exposure for this study is "regular pumping" (not further defined by the parent study). On the month 2 questionnaire, mothers responded to the question: "Are you now pumping milk on a regular schedule?" and "How old was your baby when you first began pumping on a regular schedule?" (CDC 2014). Less than 10% of month 2 questionnaires (intended to be completed at about 8.6 weeks) were completed at 13 or more weeks after birth.

All mothers who were not pumping on a regular schedule, not pumping at all, or who began regularly pumping at or after nine weeks were considered unexposed (non-regular/non-pumpers). *Outcome assessment:* The main outcomes of interest were achievement of BMF and exclusive BMF intentions. Women reported intentions on the prenatal questionnaire in response to: "How old do you think your baby will be when you completely stop breastfeeding?" (answered in months) and "How old do you think your baby will be when you first feed him or her formula or any other food besides breast milk?" (answered in categories: less than one month; 1 to 2 months; 3 to 4 months; 5 to 6 months; 7 to 9 months; more than 9 months) (CDC 2014).

On follow-up questionnaires, respondents reported infant's age when the respondent stopped breastfeeding and pumping milk (not necessarily when the infant stopped receiving breast milk). Although there is a growing body of research that distinguishes between feeding at the breast and expressing milk (e.g., Geraghty & Rasmussen 2010), the IFPS II survey did not distinguish between the two practices when ascertaining breastfeeding duration. Therefore, "achievement of BMF intention" refers to when mothers' practices of breastfeeding and pumping milk ceased, compared to when they stated prenatally that they would stop breastfeeding. CDC imputed missing values for BMF duration (approximately 6% of original study population) based on responses to food frequency questions (CDC 2012); we accepted and used those imputations in our analysis. We created a variable to compare actual BMF duration to a woman's intended BMF duration, reported prenatally, to indicate if a woman achieved her intended BMF duration.

Exclusive BMF was measured by each questionnaire through food frequency questions, e.g., "In the past 7 days how often was your baby fed each food listed below?" followed by a list of items (CDC 2014). We used the IFPS II dataset variable for exclusive BMF duration that estimates an infant's age at the mid-point between the last questionnaire that indicated exclusive

BMF and the first questionnaire that indicated not exclusively BMF. Just as for BMF, we created a variable to compare actual exclusive BMF duration to a woman's intended exclusive BMF duration, to indicate if a woman achieved her intended exclusive BMF duration.

Covariates: To make the exposure groups as comparable as possible given the limitations of observational data, we first created a directed acyclic graph (DAG; Greenland *et al.* 1999), informed by literature, expert consultation, and the Theory of Planned Behavior (Bai *et al.* 2011), to identify a sufficient adjustment set of covariates (Dagitty v. 2.3) to remove confounding. The covariates (described in Table 1) were: household income, maternal education, maternal race-ethnicity, previous breastfeeding experience, prenatal intention to breastfeed, child care plans, planning to return to work, breastfeeding initiation and early practices (index of practices in the hospital or birth center that could affect breastfeeding: pacifier use, breastfeeding within the first hour, feeding other substances to infant, rooming in, breastfeeding support, referral for post-partum support, formula gift bag), professional breastfeeding support if needed, work, child care arrangement, infant age when mother returned to work, work environment (index of unfavorable experiences: negative comments from coworker; negative comments from supervisor; difficulty arranging break time, place to pump, or place to store milk; difficulty carrying pumping equipment; worry about keeping job because of breastfeeding; worry about continuing to breastfeed because of job; embarrassed among coworkers or supervisor), and workplace support.

Analysis: To address potential confounding from a large number of confounders, we calculated inverse-probability (IP) of exposure weights, following methods recommended by Cole and Hernán (2008). The parameters produced by a weighted regression model have been used to estimate the average causal effect under certain assumptions (Cole & Hernán 2008; Buchanan *et al.* 2014). We also tested suspected effect measure modification by obesity, income, alignment of

BMF intention with recommended duration, work environment and workplace support (a=0.05). We stratified the analyses by work status, using this question: "Did you work for pay any time during the past 4 weeks?" on the month 2 survey to ascertain work status (CDC 2014). Finally, we qualitatively examined regular pumpers further, to identify characteristics related to pumping practice.

We used multiple imputation with 100 replications to address missing exposure, duration and covariate values with predictors including potential confounders, effect measure modifiers and factors affecting selection into the study (described below). About 20% of respondents were missing values for more than one covariate. In addition, about 20% of respondents were missing BMF duration and about 5% were missing exclusive BMF duration, because they dropped out of the study. We estimated adjusted risk ratios for achieving BMF and exclusive BMF intentions, according to pumping status with weighted log-binomial models using the imputed dataset (SAS, Version 9.4, Cary, NC, USA).

Bias could be caused by women stopping BMF or exclusive BMF before month 2, when this study began. To address that potential selection bias, we created and applied IP selection weights, using methods similar to those reported by Bengtson *et al*. (2016). We considered covariates associated with BMF and exclusive BMF when our study began and then estimated the weights as the inverse probability of BMF and exclusive BMF (separately). The weights equation for BMF contained these predictors: maternal age, college degree, experience of breastfeeding-related pain in the first two weeks, marital status, and plans to return to work within the first nine weeks. The weights equation for exclusive BMF contained these predictors: college degree, marital status, and plans to return to work within the first nine weeks. We stabilized the weights by the marginal probability of being in this study, to reduce the weights of

exposed women with a low probability of exposure and unexposed women with a high probability of exposure (Xu *et al.* 2010). We multiplied the selection weights by the IP weights for confounding (as described above) and then used the combined weights in the statistical models. All weights were created in the imputed dataset.

Results

The majority of women in this study were white, married, had a term infant, had breastfed previously, and experienced breastfeeding problems in the early postpartum period (Table 5). The median intended duration for mothers that BMF was 10 - 12 months. The median intended duration for mothers who were exclusively BMF was 5 to 6 months (Table 5; Figures 10 and 11).

Most regular pumpers who reported BMF on the month 2 questionnaire had a college degree, worked in the third trimester but not at month 2, were planning to return to work in the first year, had child care plans in which mother and infant would be separated, and sought help for breastfeeding problems if they experienced them (Table 5). Most non-regular/non-pumpers who were BMF did not have a college degree, were not working at the time of study enrollment or at month 2, and had childcare plans in which mother and infant were together. Half of them were not planning to return to work in the first year (Table 5).

Likewise, most regular pumpers who were exclusively BMF at month 2 had a college degree, worked in the third trimester but were not working at month 2, were planning to return to work in the first year, had child care plans in which mother and infant would be separated, and sought help for breastfeeding problems if they experienced them (Table 5). Most non-regular/non-pumpers who reported exclusive BMF were not working at the time of study enrollment or at month 2, had childcare plans in which mother and infant were together, and

were not planning to return to work in the first year. Half of them did not have a college degree (Table 5).

The IP of exposure weights achieved the goal of balancing covariates between exposure groups in the weighted sample (mean~1.00; Tables 6 and 7). We found that regular pumpers were 21% less likely to achieve their intention than non-regular/non-pumpers (Risk Ratio (RR) 0.79; 95% Confidence Interval (CI) 0.67 – 0.94 (Table 6)). Among working women, the RR was 1.08 (95% CI 0.81 – 1.43). Among non-working women, regular pumpers were 31% less likely to achieve their BMF intention than non-regular/non-pumpers (RR 0.69; 95% CI 0.56 – 0.85). We did not observe a statistically significant effect on achieving exclusive BMF intentions overall (RR 1.05; 95% CI 0.84 – 1.31) or by work status (Table 7).

Our examination of effect measure modification for obesity, household income, work environment, workplace support, and alignment of prenatal intention with recommended duration revealed that household income and alignment of prenatal intention with recommended BMF duration modified the estimated effect of regular pumping on achievement of BMF intention ($p<0.05$). Among women with a household income lower than the study median, regular pumpers were less likely to achieve BMF intention than non-regular/non-pumpers (RR 0.63; 95% CI 0.47 – 0.86). There was no observed difference among women with a household income equal to or greater than the study median value (RR 0.93; 95% CI 0.76 – 1.14). Among women whose prenatal intentions aligned with the recommended 12-month duration for BMF, regular pumpers were less likely than non-regular/non-pumpers to meet their intentions (RR 0.57; 95% CI 0.40 – 0.82). There was no observed difference among women whose intentions fell short of the recommendation (RR 0.93; 95% CI 0.78 – 1.11). We did not find interactions in the exclusive BMF models.

When we examined the characteristics of regular pumpers we found that, among women who were BMF, or exclusively BMF, and not working at month 2, about 45% were planning to return to work within the first year (Table 8). The main reasons for regularly pumping among non-workers at month 2 were for "someone else to feed the baby" (76% BMF and 82% of exclusive BMF) and to have "an emergency supply" (57% BMF and 67% exclusive BMF).

Table 5: Maternal and infant descriptive characteristics for 1512 U.S. mothers who made a prenatal intention to breastfeed, in the IFPS II, 2005-7.

	Any breast milk feeding at two months (N=1512)[a]		**Exclusive breast milk feeding at two months (N=867)[a]**	
	Regularly pumping[b] (n=338)	Not regularly pumping (n=1136)	Regularly pumping[c] (n=175)	Not regularly pumping (n=676)
	N(%) Mean (SD)	N(%) Mean (SD)	N(%) Mean (SD)	N(%) Mean (SD)
Age				
Maternal age at study enrollment[d]	29.6 (4.7)	29.6 (5.2)	29.7 (4.5)	29.6 (4.9)
Income				
Median household	$50,000 – $59,999	$45,000 – $49,999	$60,000 – $74,999	$45,000 - $49,999
Education				
College graduate or more	195 (58%)	497 (44%)	108 (62%)	335 (50%)
Some college or less	130 (38%)	593 (52%)	62 (35%)	321 (47%)
Missing	13 (4%)	46 (4%)	5 (3%)	20 (3%)
Race/Ethnicity				
White, non-Hispanic	277 (82%)	961 (85%)	148 (85%)	598 (88%)
Black, non-Hispanic	13 (4%)	36 (3%)	7 (4%)	13 (2%)
Hispanic	18 (5%)	66 (6%)	9 (5%)	25 (4%)
Other	20 (6%)	52 (5%)	6 (3%)	29 (4%)
Missing	10 (3%)	21 (2%)	5 (3%)	11 (2%)
Parity				
Other live births	0.9 (1.0)	1.4 (1.3)	0.8 (0.9)	1.4 (1.2)
Missing	7 (2%)	13 (1%)	3 (2%)	6 (1%)
Marital status				
Married	276 (82%)	951 (84%)	145 (83%)	603 (89%)
Single/Divorced/ Separated	47 (14%)	143 (13%)	24 (14%)	55 (8%)
Missing	15 (4%)	42 (4%)	6 (3%)	18 (4%)
Previous breastfeeding experience				
Yes	182 (54%)	838 (74%)	90 (51%)	518 (77%)
No	145 (43%)	275 (24%)	78 (45%)	148 (22%)

Missing	11 (3%)	23 (2%)	7 (4%)	10 (1%)
Maternal BMI (pre-pregnancy)				
Underweight	10 (3%)	48 (4%)	7 (4%)	34 (5%)
Normal	165 (49%)	542 (48%)	86 (49%)	350 (52%)
Overweight	101 (30%)	289 (25%)	52 (30%)	158 (23%)
Obese	60 (17%)	243 (21%)	29 (17%)	127 (19%)
Missing	2 (1%)	14 (1%)	1 (1%)	7 (1%)
Working at study enrollment[d]				
Yes	247 (73%)	489 (43%)	128 (73%)	270 (40%)
No	87 (26%)	635 (56%)	45 (26%)	398 (59%)
Missing	4 (1%)	12 (1%)	2 (1%)	8 (1%)
Prenatal intention to breastfeed[e]				
Months (median)	10.0	12.0	5-6	5-6
Missing	0	0	0	0
Child care plans				
Mother/infant together	93 (28%)	753 (61%)	48 (27%)	457 (68%)
Mother/infant separated	197 (58%)	331 (27%)	104 (59%)	135 (20%)
Combination/not sure	46 (14%)	143 (12%)	22 (13%)	79 (12%)
Missing	2 (1%)	8 (1%)	1 (1%)	5 (1%)
Planning to return to work				
Within 9 weeks	152 (45%)	282 (25%)	75 (43%)	140 (21%)
After 9 weeks but within first year	112 (33%)	279 (25%)	60 (34%)	160 (24%)
Not planning to return in first year	71 (21%)	566 (50%)	38 (22%)	369 (55%)
Missing	3 (1%)	9 (1%)	2 (1%)	7 (1%)
Breastfeeding initiation and early practices				
Mean score[f]	3.1 (1.4)	3.1 (1.5)	2.9 (1.4)	2.8 (1.4)
Missing	8 (2%)	31 (3%)	3 (2%)	22 (3%)
Late pre-term status				
Yes	18 (5%)	32 (3%)	8 (5%)	8 (1%)
No	329 (95%)	1104 (97%)	167 (95%)	668 (99%)
Breastfeeding problems				
No	41 (12%)	153 (13%)	22 (13%)	113 (17%)
Yes	296 (88%)	982 (86%)	153 (87%)	563 (83%)
Got help	193 (57%)[g]	478 (42%)[g]	102 (58%)	294 (43%)
Did not get help	102 (30%)	497 (44%)	51 (29%)	268 (40%)
Missing	1 (0)	1 (0)	0	1 (0)
Post-partum depression				
Average score	6.3 (4.1)	6.5 (4.4)	6.0 (4.1)	6.0 (4.1)
Score $\geq$13[h]	27 (8%)	104 (9%)	12 (7%)	41 (6%)
Score <13	303 (90%)	998 (88%)	157 (90%)	619 (92%)
Missing	8 (2%)	34 (3%)	6 (3%)	16 (2%)

Working[i]				
Yes	157 (46%)	231 (20%)	74 (42%)	117 (17%)
No	177 (52%)	853 (75%)	101 (58%)	530 (78%)
Missing	4 (1%)	52 (5%)	0	29 (4%)
Child care				
Mother and infant may be separated for feeding	134 (40%)	108 (10%)	65 (37%)	38 (6%)
Mother and infant are never separated for feeding	20 (6%)	118 (10%)	9 (5%)	76 (11%)
Missing	7 (2%)	57 (5%)	0	32 (5%)
Not working	177 (52%)	853 (75%)	101 (58%)	590 (78%)
Hostile work environment				
Mean score[j]	1.2 (1.6)	0.6 (1.3)	1.2 (1.6)	0.5 (1.2)
Missing	37 (11%)	92 (8%)	14 (19%)	17 (15%)
Not working	177 (52%)	853 (75%)	101 (58%)	530 (78%)
Infant age when mother returned to work				
≤8 weeks	83 (25%)	110 (10%)	36 (37%)	60 (9%)
>8 weeks	48 (14%)	89 (8%)	26 (15%)	44 (7%)
Missing	30 (9%)	84 (7%)	12 (7%)	42 (6%)
Not working	177 (52%)	853 (75%)	101 (58%)	530 (78%)
Workplace support				
Not at all supportive	4 (1%)	5 (0)	2 (1%)	2 (0)
Not too supportive	14 (4%)	13 (1%)	4 (2%)	3 (0)
Somewhat supportive	40 (12%)	37 (3%)	17 (10%)	17 (3%)
Very supportive	70 (21%)	119 (10%)	39 (22%)	72 (11%)
Missing	33 (10%)	109 (10%)	12 (16%)	52 (8%)
Not working	177 (52%)	853 (75%)	101 (58%)	530 (78%)
Breast milk feeding duration (weeks)	32.4 (15.4)	37.2 (16.3)	15.3 (6.4)	16.9 (6.9)
Achieved intention	112 (33%)	437 (38%)	54 (31%)	217 (32%)

[a]Missing=5
[b]Missing=38
[c]Missing=16; exclusive breastfeeding is a subset of any breastfeeding
[d]Women enrolled during the third trimester.
[e]Measured in months for any breastfeeding and by month range for exclusive breastfeeding (median reported)
[f]This variable comprises practices in the hospital or birth center, as reported on the neonatal questionnaire (IFPS II): pacifier use; breastfed in the first hour; fed infant substances other than breast milk; baby slept in mother's room; mother received breastfeeding support; received referral for post-partum breastfeeding support; and received gift bag with formula sample or coupon.
[g]Missing one response for regular pumpers; missing 8 (1%) for non-regular pumpers
[h]Referral for depression treatment is recommended for score of 13 or higher on the Edinburgh Postpartum Depression Screening tool.
[i]Worked sometime in past four weeks, from time completed Month 2 questionnaire
[j]This variable comprises circumstances encountered in the workplace, as reported on the 3-month questionnaire (IFPS II): coworker made negative comments or complained to mother about breastfeeding; employer or supervisor made negative comments or complained about breastfeeding; hard to arrange break time to breastfeed or pump milk; hard to find a place to breastfeed or pump milk; hard to arrange a place to store pumped milk; hard to carry the equipment needed to pump milk at work; worried about keeping my job because of breastfeeding; worried about continuing to breastfeed because of job; felt embarrassed among coworkers, supervisor, or employer because of breastfeeding; 408 working mothers

Figure 10: Breastfeeding intention for 1512 women who were breast milk feeding at Month 2, in the IFPS II, 2005-7.

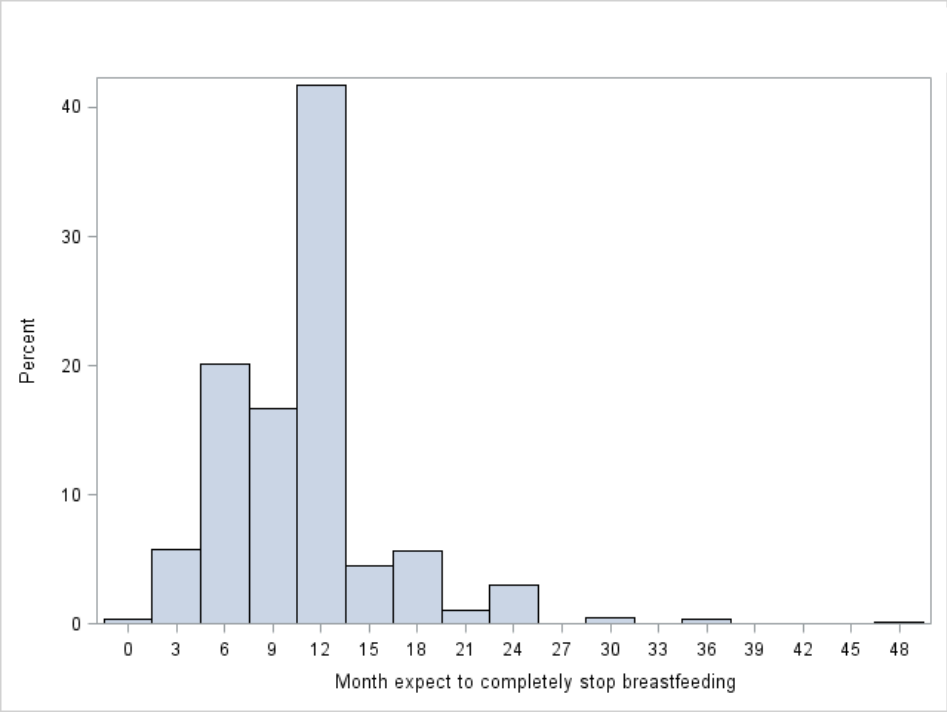


Figure 11: Exclusive breastfeeding intention for 867 women who were exclusively breast milk feeding at Month 2, in the IFPS II, 2005-7.

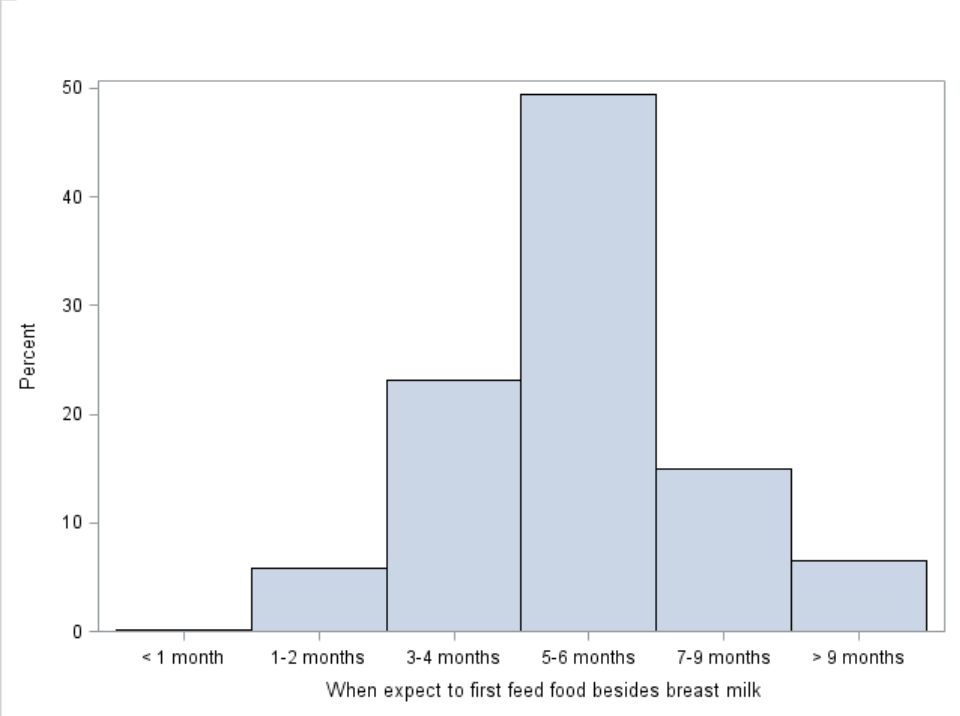


Table 6: Risk ratios for the effect of regular pumping on achieving breastfeeding intention, for 1512 women in the IFPS II, 2005 – 2007.

	Crude[a]	Weighted[b]
Overall	0.92 (0.79 – 1.06)[c]	0.79 (0.67 – 0.94)
Work status		
Working at two months	1.11 (0.88 – 1.40)	1.08 (0.81 – 1.43)
Not working	0.82 (0.67 – 1.00)	0.69 (0.56 – 0.85)

[a]Weighted for selection (mean=1.00; range: 0.78 – 4.32).
[b]Weighted to control for confounding by household income, education, white race-ethnicity, prenatal breastfeeding intention, child care plan, plan to return to work within 9 weeks, early breastfeeding practices, accessing help for breastfeeding problems, infant age when mother returned to work, mother-infant sometimes separated for feeding, work, late pre-term status, work environment, and workplace support (mean=1.00; range: 0.24 – 8.66). Also weighted for selection.
[c]95% confidence interval

Table 7: Risk ratios for the effect of regular pumping on achieving exclusive breastfeeding intention, for 867 women in the IFPS II, 2005 – 2007.

	Crude[a]	Weighted[b]
Overall*	0.99 (0.80 – 1.23)[c]	1.05 (0.84 – 1.31)
Work status		
Working at two months	1.20 (0.87 – 1.66)	1.36 (0.95 – 1.95)
Not working	0.77 (0.55 – 1.08)	0.70 (0.69 – 1.22)

[a]Weighted for selection (mean= 1.00; range: 0.63 – 3.67)
[b]Weighted to control for household income, education, white race-ethnicity, prenatal exclusive breastfeeding intention, child care plan, plan to return to work within 9 weeks, early breastfeeding practices, accessing help for breastfeeding problems, infant age when mother returned to work, mother-infant sometimes separated for feeding, work, late pre-term status, work environment, and workplace support; (mean=1.01; range: 0.21 - 28.98). Also weighted for selection.
[c]95% confidence interval

Table 8: Maternal and infant descriptive characteristics for 338 U.S. women who reported a prenatal breastfeeding intention, by work status, in the IFPS II, 2005-2007

	Any breast milk feeding at two months and regularly pumping (N=338)		Exclusive breast milk feeding at two months and regularly pumping (N=175)[a]	
	Working[b] (n=157)	Not working (n=177)	Working[c] (n=74)	Not working (n=101)
	N(%) Mean (SD)	N(%) Mean (SD)	N(%) Mean (SD)	N(%) Mean (SD)
Age				
Maternal age at study enrollment[d]	29.3 (4.7)	29.9 (4.6)	29.6 (4.5)	29.7 (4.6)
Income				
Median household	$50,000 – $59,999	$50,000 – $59,999	$50,000 – $59,999	$60,000 - $74,999

Education				
College graduate or more	93 (59%)	100 (57%)	46 (62%)	62 (61%)
Some college or less	59 (38%)	70 (40%)	28 (38%)	34 (34%)
Missing	5 (3%)	7 (4%)	0	5 (5%)
Race/Ethnicity				
White, non-Hispanic	129 (82%)	145 (82%)	64 (86%)	84 (83%)
Black, non-Hispanic	5 (3%)	8 (5%)	2 (3%)	5 (5%)
Hispanic	8 (5%)	10 (6%)	5 (7%)	4 (4%)
Other	11 (7%)	8 (5%)	2 (5%)	4 (4%)
Missing	4 (3%)	6 (3%)	1 (1%)	4 (4%)
Parity				
Other live births	0.9 (1.0)	0.8 (1.0)	0.9 (0.9)	0.7 (1.0)
Missing	3 (2%)	3 (2%)	1 (1%)	2 (2%)
Marital status				
Married	127 (81%)	148 (84%)	61 (82%)	84 (83%)
Single/Divorced/ Separated	25 (16%)	20 (11%)	13 (18%)	11 (11%)
Missing	5 (3%)	9 (5%)	0	6 (6%)
Previous breastfeeding experience				
Yes	92 (59%)	87 (49%)	45 (61%)	45 (45%)
No	61 (39%)	84 (47%)	27 (36%)	51 (50%)
Missing	4 (3%)	6 (3%)	2 (3%)	5 (5%)
Prenatal intention to breastfeed[e]				
Months (median)	10.0	10.0	5-6	5-6
Missing	0	0	0	0
Planning to return to work				
Within 9 weeks	117 (75%)	34 (19%)	57 (77%)	18 (18%)
After 9 weeks but within first year	32 (20%)	79 (45%)	14 (19%)	46 (46%)
Not planning to return in first year	7 (4%)	62 (35%)	2 (3%)	36 (36%)
Missing	1 (1%)	2 (1%)	1 (1%)	1 (1%)
Breastfeeding initiation and early practices				
Mean score[f]	3.1 (1.4)	3.1 (1.4)	2.9 (1.5)	2.8 (1.3)
Missing	1 (1%)	7 (4%)	1 (1%)	2 (2%)
Breastfeeding problems				
No	25 (16%)	15 (8%)	13 (18%)	9 (9%)
Yes	132 (84%)	161 (91%)	61 (82%)	92 (91%)
Got help	80 (51%)	111 (63%)	31 (42%)	66 (65%)
Did not get help	52 (33%)	49 (28%)	30 (41%)	26 (26%)
Missing	0	1 (1%)	0	0
Post-partum depression				
Average score	6.4 (3.7)	6.1 (4.4)	6.3 (3.7)	5.9 (4.3)

Score ≥13[g]	7 (4%)	17 (10%)	4 (5%)	8 (8%)
Score <13	148 (94%)	155 (88%)	68 (92%)	89 (88%)
Missing	2 (1%)	5 (3%)	2 (3%)	4 (4%)
Reasons for pumping in past two weeks[h]				
Engorgement	50 (32%)	70 (40%)	25 (34%)	37 (37%)
Sore nipples	5 (3%)	8 (5%)	3 (4%)	6 (6%)
Increase milk supply	66 (42%)	82 (46%)	30 (41%)	44 (44%)
For someone else to feed baby	133 (85%)	134 (76%)	69 (93%)	83 (82%)
Does not want to breastfeed or infant cannot	55 (34%)	82 (46%)	19 (26%)	38 (38%)
To maintain supply when infant could not nurse (separation or infant illness)	74 (47%)	49 (28%)	31 (42%)	27 (27%)
To mix with food	9 (6%)	10 (6%)	0	1 (1%)
To donate	3 (2%)	1 (1%)	2 (3%)	1 (1%)
To have an emergency supply	58 (37%)	100 (57%)	34 (46%)	68 (67%)
Missing	0	4 (2%)	0	1 (1%)
Breast milk feeding duration (weeks)	35.5 (15.6)	32.7 (15.3)	16.1 (5.2)	15.6 (6.4)
Missing	27 (17%)	30 (17%)	6 (8%)	3 (3%)
Achieved intention	56 (36%)	55 (31%)	28 (38%)	26 (26%)

[a]Exclusive breastfeeding is a subset of any breastfeeding
[b]Worked sometime in past four weeks, from time completed Month 2 questionnaire; Missing=4
[c]Worked sometime in past four weeks, from time completed Month 2 questionnaire; Missing=0
[d]Women enrolled during the third trimester.
[e]Measured in months for any breastfeeding and by month range for exclusive breastfeeding (median reported)
[f]Variable composition described in Table S.1.
[g]Referral for depression treatment is recommended for score of 13 or higher on the Edinburgh Postpartum Depression Screening tool.
[h]Respondents could choose more than one reason.

Discussion

In this study we estimated the effect of regular breast milk pumping in the early postpartum period on achieving prenatal BMF and exclusive BMF intentions, overall and among working and non-working women in the U.S. We found that women (overall and non-working) who pumped regularly were less likely to achieve their BMF intentions than women who did not regularly pump. We did not observe an effect among working women. We also did not observe statistically significant effects for exclusive BMF overall, or by work status; although, our

analysis suggested a possible protective effect among working women. In addition, among women with lower household incomes, regular pumpers were much less likely to achieve their BMF intentions than non-regular/non-pumpers. Among women who intended to BMF for at least 12 months, regular pumpers were much less likely to achieve their intentions than non-regular/non-pumpers.

Women who are regularly pumping in the early postpartum period are at risk of not achieving their BMF goals, particularly when they are not working, live in a lower income household, or intend to breastfeed for the recommended duration of 12 or more months (AAP 2012). In addition, early, regular pumping may not help working women to achieve their BMF or exclusive BMF intentions.

We found that most regular pumpers, whether working at month 2 or not, pumped for someone else to feed their infants and to have an emergency supply, both of which could signal preparation for separation due to current or future work status. We did not examine work plans by breastfeeding intention; however, we found that most regular pumpers who reported BMF or exclusively BMF in our study had planned to return to work within the first year, compared to about half of the non-regular/non-pumpers. Other studies examined the effect of work on mothers' breastfeeding intentions and on achieving breastfeeding intentions, but not with regards to pumping practices. Working women may intend to BMF for what is a realistic duration for them even though it falls short of recommendations for optimal health. A study using similar data found that mothers who planned to return to work before three months postpartum, or who returned to work full-time, were less likely to intend to exclusively breastfeed than mothers returning to work later or returning part-time (Mirkovic *et al.* 2014).

We found that early, regular pumping neither helped nor hindered working women's achievement of their BMF and exclusive BMF intentions. That finding could have resulted from a statistical balancing of outcomes for working women for whom pumping helped to achieve their intentions and for women for whom pumping did not help. For working women, logistical and psychological challenges related to arranging time and space to pump could contribute to a reluctance to pump and also to pumping ineffectiveness, because stress interferes with lactation (Lau 2001). Some working women may have pumped less often at work than their infants' feeding patterns, or their pumps may have been ineffective. Thus, although they may have maintained breastfeeding when they were together with their infants, infrequent or insufficient removal of breast milk when separated from their infants would cause production to decrease (Mannel & Walker 2013; Baker & Lamb 2013). Decreased production could lead to early BMF cessation as an infant becomes increasingly reliant on breast milk substitutes (Mannel & Walker 2013; Baker & Lamb 2013).

The TPB guided our analyses and is particularly well suited for research about breastfeeding behaviors because those behaviors are not completely volitional, in that they depend on a range of maternal and infant factors (Wambach 1997). The TPB posits a social-behavioral mechanism for the formation of BMF intentions, which have been found to predict breastfeeding outcomes (Bonuck *et al.* 2005; Duckett *et al.* 1998). BMF research underpinned by the TPB suggested different avenues for intervention during the prenatal period when BMF intentions are formed, by enhancing women's confidence and changing their attitudes about breastfeeding, as well as assessing their perceived behavioral control and potential barriers to breastfeeding (Wambach 1997). Our study did not examine the factors underlying intentions. Other research found that the ease of pumping provided a sense of behavioral control for some

women, and that drove their intentions to exclusively BMF for the recommended duration (Bai *et al.* 2011). In our study, exclusive BMF intentions were within the recommended range among both regular and non-regular/non-pumpers, but BMF intentions fell well short of the 12-month recommended duration.

Since prenatal BMF intention has been found, repeatedly, to predict BMF duration (Donath *et al.* 2003), (with some exceptions e.g., Wambach 1997), health care providers and family supporters should know how women's attitudes, social norms and perceived behavioral control—all predictors of behavioral intentions according to the TPB--could be altered so that their BMF intentions better align with health recommendations, and so that they can support women to achieve their BMF intentions. We found that the estimated effect of regular breast milk pumping on achievement of BMF and exclusive BMF intentions can vary with circumstances, and may be dependent on the intensity of BMF (exclusive versus partial), a woman's working status, household income, and alignment of BMF intention with recommendations. Those factors should be considered by those seeking to support BMF among women who will be regularly pumping in the early postpartum period.

The strengths of this study include its use of behavioral theory (TPB), literature, and expert opinion to create the DAG that guided our analyses. We used IP weights to control confounding, which better handled the number of covariates in our statistical models than would a typical regression approach, and enabled us to estimate marginal population effects. Similar to typical regression approaches, this methodology assumed a positive probability for each level of exposure at each level of the covariates, a well-defined exposure, a correctly specified model, and no unmeasured confounding or selection bias (Cole & Hernán 2008). Although we believe

that our statistical models are well specified, we acknowledge the possibility of unknown confounding.

There are some limitations to this study. We addressed selection bias with IP weights, but some selection bias is inherent to the parent study because participants were selected from members of a consumer panel and other inclusion criteria regarding infant health, which limit the generalizability of our findings. The parent study population was better off than the general U.S. maternity population (CDC 2012), so our results are likely conservative estimates, because we found that, among women with a lower household income, regular pumpers were less likely than non-regular/non-pumpers to achieve their BMF intentions. There may still be confounding by indication (more selection bias), if women did not intend to BMF because they knew that they would be returning to work early and could not combine BMF with working, or otherwise anticipated a lack of support (social norm) or control over their ability to BMF.

There are other limitations to this study. There were missing data for exposure, outcome, and covariate measures, which we addressed with multiple imputation. Our measure for exclusive BMF assessed behavior over the past seven days, and we assumed that this practice was constant since the prior survey. That is a common way to measure exclusive BMF practice, but it is imperfect. Exclusive BMF intention was reported in a range of months, which is imprecise. The survey question refers to "breastfeeding" intention but does not specifically refer to expressing milk and it is unclear if women interpreted the question to apply to both practices. Some questionnaires were not completed at the time they were received, which may have caused possible misclassification or recall bias. About 10% of women completed the month 2 questionnaire when their infants were more than 13 weeks old.

Conclusions: Women who regularly pump in the early postpartum period may be less likely to achieve their BMF intentions compared to women who do not, and regular pumping may not help working women to achieve their BMF intentions. With increased support for pumping under the ACA (AAP 2013), this study could serve as a baseline for evaluating the effect of regular pumping on women's attainment of their BMF intentions under those protections. Specialized support for pumping may be needed prenatally when women who anticipate pumping are forming their intentions, and postnatally, when they begin regularly pumping. Women with lower incomes, those who intend to BMF for 12 or more months, and those who may be preparing to return to work may particularly benefit from specialized postnatal support for pumping. To be able to intervene prenatally, when women are forming their BMF intentions, it is critical to understand how pumping, and anticipation of pumping, may interact with women's attitudes toward breastfeeding, social norms, and perceived behavioral control, which may affect their BMF intentions and outcomes.

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CHAPTER 5: CONCLUSIONS

Section 5.1 Recapitulation of study aims, findings, and degree to which the goals of the doctoral research have been met

These studies were designed to estimate the effect of early, regular breast milk pumping on time to both BMF (Aim 1) and exclusive BMF (Aim 1a) cessation and achievement of BMF (Aim 2) and exclusive BMF (Aim 2a) intentions. Those Aims where achieved as described, below.

Results synthesis

Overall, early, regular pumping did not prolong BMF or exclusive BMF duration or help women to achieve their BMF or exclusive BMF intentions, compared to non-regular pumping. For some women, initiating regular pumping in the first two months may have even led them to BMF a shorter amount of time than if they had had other options. Surprisingly, the group in which there was little effect of early, regular pumping was mothers who returned to work in the first 2 months. Among these women, early regular pumping had no effect. In contrast, women who began regularly pumping before returning to work, and those early, regular pumpers who did not plan to work, experienced a consistently detrimental effect of early, regular pumping. These non-working early, regular pumpers BMF and exclusive BMF for a shorter length of time and were less likely to meet their BMF intentions than non-regular pumpers.

Despite policy intentions (AAP 2013) and national goals (DHHS 2017), regular pumping may not increase working women's BMF and exclusive BMF durations, compared to non-regular/non-pumping. In the first study (Paper 1), I found that regular pumpers were more likely to stop BMF (by 62%) and exclusive BMF (by 14%) than non-regular/non-pumpers, within the recommended time frames (12 months for BMF and six months for exclusive BMF; AAP 2012). However, I found that the effect of regular pumping on time to BMF and exclusive BMF cessation varied by work status. For working women, in particular, regular pumping had an estimated effect near null; however, among non-working women, regular pumpers were at least twice as likely to stop BMF as non-regular/non-pumpers, with no observed effect on exclusive BMF cessation.

These findings suggest that policy protections for BMF that focus only on pumping may not be effective for working women. The surprisingly strong estimated effect for non-working women may be explained by the fact that most regular pumpers that were not working at month 2 (~65%) had planned to return to work within the first year. Many of those women were likely pumping regularly to build a supply of milk to use upon their return to work. This suggests that a stronger effect could be observed among working women if the exposure period were extended by one or more months. That would capture more regular pumpers as working and may yield the expected effect. However, my research question was concerned with early (in the first two months), regular pumping.

In the second study, I estimated the risk that regular breast milk pumping in the early postpartum period, compared to non-regular/non-pumping, posed for achieving prenatal BMF and exclusive BMF intentions, overall and among working and non-working women. I found that regular pumpers, including those not working, were less likely (21% and 31%, respectively)

to achieve their BMF intentions than non-regular/non-pumpers. These results suggest that, in the early postpartum period, regular pumpers, including those not working, are at risk of not achieving their BMF goals.

There was no observed effect among working women; it seems that early, regular pumping may not aid working women in achieving their BMF and exclusive BMF intentions. In addition, I did not observe statistically significant effects for exclusive BMF, indicating that regular pumping neither helped nor hindered women to achieve their exclusive BMF intentions. I also found that, among women with lower household incomes, regular pumpers were 37% less likely than non-regular/non-pumpers to achieve their BMF intentions. Among women intending to BMF for the recommended duration (at least 12 months), regular pumpers were 43% less likely than non-regular/non-pumpers to achieve their BMF intentions. Regular pumpers living in a lower income household or intending to breastfeed for 12 or more months have a higher risk of not achieving their BMF intentions than non-regular/non-pumpers. Those women may need specialized support which could include more intensive support from the WIC program (for low-income women), and more resources (educational, planning, counseling, etc.) for women who aim to BMF for the recommended duration, both pre- and post-natally.

Obesity could have a negative impact on breastfeeding practices through sub-optimal positioning, which could cause pain during breastfeeding, and through delayed milk synthesis due to a diminished response to prolactin (Rasmussen & Kjolhede 2004). However, I did not find effect measure modification by obesity for BMF ($p=0.19$) or exclusive BMF ($p=0.07$). I used a conservative *alpha*=0.05 for the interaction tests, which could have limited further exploration into potential effect measure modifiers. In addition, the prevalence of pre-pregnancy obesity in this study population (~18%) was lower than in the general maternity population in the U.S.

(~25%; Branum *et al.* 2016). Obesity was self-reported in this study and may have been under-reported. It should be investigated in future studies, including a population with a representative prevalence of obesity.

Overall, regular pumping neither benefitted nor harmed women working at month 2 in either study, compared to non-regular pumping. Thus, I found some evidence that pumping alone is insufficient to assist working women to BMF and exclusively BMF for the recommended durations and to meet their own BMF and exclusive BMF goals. I controlled for separation of mother and infant through child care but I was not able to assess women's work schedules in detail, e.g., if they worked full- or part-time at two months. One study using these IFPS II data found that women who returned to work full-time after 12 weeks had a shorter BMF duration than those working part-time; however, there was no difference in duration by work status among women returning to work before 12 weeks (which applied to the women in my study).

That finding of shorter duration for women returning to full-time work after 12 weeks may partially explain my findings related to non-working women. I found that non-working regular pumpers had greater hazards of stopping BMF than non-regular pumpers, and were less likely to meet their BMF intention than non-regular pumpers. Among women who were not working at month 2, 45% of regular pumpers had planned to return to work between three and 12 months. Thus, many non-working regular pumpers were likely pumping in preparation for returning to work. Those women experience a "double burden" of both feeding at the breast and pumping regularly to ensure a supply of breast milk for a future separation of infant and mother. If those women returned to work full-time and Mandal *et al.'s* (2010) findings hold, then those women would likely stop BMF before their non-working counterparts.

In addition, 11% of non-working regular pumpers had a clinically significant post-partum depression score, and that depression may have contributed to early BMF cessation (Henderson *et al.* 2003). Those women may have been planning to return to work or pumping for other reasons. Women who are not separated from their infants but are regularly pumping for reasons indicated by maternal or infant health, or preference, could experience particular challenges related to fatigue and doubts about their abilities to provide sustenance for their infants.

These studies' findings about the effects of early, regular pumping on BMF and exclusive BMF cessation and achievement of intentions, point to the need to review current support mechanisms for women who are regularly pumping in the early postpartum period. First, specialized support for pumping could be helpful to all women prenatally, when women are forming their intentions and anticipating pumping, and also postnatally, when women are pumping. That support should be specialized to the particular reasons for pumping, e.g., women preparing to return to work need a different kind of support than women who are pumping because their infant has trouble feeding at the breast. More research is needed to determine how best to support regular pumpers in the early post-partum period. Workplaces could help women prepare for pumping by having a clear explanation of relevant policies accessible to employees and by encouraging women to avail of policy protections and to seek clarification or assistance, if needed. Secondly, regular pumpers with low incomes, who intend to BMF for at least 12 months, and who are not working in the early postpartum period (but may be preparing to return to work) may particularly benefit from specialized support for pumping postnatally. Third, to intervene when women are making their BMF intentions, it is important to understand how pumping, and the anticipation of pumping and the work environment, may affect women's

perceived behavioral control, attitudes toward BMF and social norms around BMF, which may ultimately affect BMF intentions and outcomes.

These studies could provide baseline measures for evaluating the effects of regular pumping on BMF practices and achievement of BMF intentions under the ACA. The findings from these studies indicate that policies that rely mainly on pumping may not have intended effects on BMF duration or achievement of BMF intentions. The surge in pump ownership under the ACA (see, e.g., Hawkins *et al.* 2017) has implications for breastfeeding practices in the U.S. It remains to be seen how pumping practices, and the population that is pumping, has changed in the U.S. since the ACA and if more protections for pumping translate to greater equity in BMF practices among all race-ethnicities and incomes, and longer BMF durations. Of course, breastfeeding is just one postnatal health outcome affected by U.S. maternity policies. There have been calls for more humane policies to protect parents and infants in the postnatal period, and those policies are estimated to benefit breastfeeding practices in addition to other health outcomes (Fein *et al.* 2008; Academy of Breastfeeding Medicine 2013).

These studies included a population of women who were "better off" than the general population, in terms of income and education, and I found that pumping was not beneficial to their BMF durations or achieving their BMF intentions, overall. There is reason to suspect that the effects of regular pumping may be more detrimental among lower-income populations, as indicated by my second study, which found that regular pumpers in lower-income households were 37% less likely to achieve their BMF intention than non-regular pumpers.

These studies add causally-oriented epidemiologic investigations of the effect of regular pumping in the early postpartum period to the literature. They answer a unique question about the effect of regular pumping on BMF and exclusive BMF cessation and achievement of

intentions in the U.S. context. As such, these studies are not directly comparable to previous studies, all of which characterized pumping differently (e.g., by frequency), and most of which were not guided by theory and did not control for all relevant confounders. The literature indicates and TPB further suggests that confounding is a major concern for research questions about BMF; a causal approach to analysis reduces those biases.

Section 5.2 Strengths

The findings of these studies are especially salient for the U.S., which lacks basic maternity protections, e.g., paid leave and affordable, high-quality child care, but supports breast milk pumping as a way to continue BMF when mothers and infants are separated due to maternal work. I did not find a detrimental nor a beneficial effect of early, regular pumping, compared to non-regular/not pumping, among working women, indicating that policies that rely solely on breast milk pumping to increase BMF durations and achievement of BMF intentions may not have their intended effects. Given that these data were collected before the ACA, these studies provide useful baseline measures to evaluate how the ACA, with its increased emphasis on breast milk pumping (AAP 2013), has affected BMF practices overall, and for working and non-working women.

Other studies have attempted to estimate the effect of breast milk pumping on BMF cessation, but were limited methodologically (e.g., by imprecise definitions and likely misclassification) or by select and small populations (e.g., milk donors). The theory-based, methodologically rigorous studies presented here utilized the abundance of relevant demographic, health, and infant feeding variables in the IFPS II to fill those gaps in the literature with credible findings that estimate the effects of regular pumping on both BMF (and exclusive BMF) cessation and achievement of BMF (and exclusive BMF) intentions.

The IFPS II is a well-documented study with longitudinal data about mother-infant pairs, including detailed information about infant feeding practices, across the U.S. I used state-of-the-art epidemiological methods to address potential biases from selection and confounding in my analyses, through multiple imputation and IP weights (Bengtson *et al.* 2016; Cole & Hernán 2008; Buchanan *et al*. 2014). With certain assumptions, the hazard ratios and risk ratios that I estimated could estimate the average casual effects of early, regular pumping on time to BMF (and exclusive BMF) cessation and on achievement of BMF (and exclusive BMF) intentions in the study population (Cole & Hernán 2008).

Section 5.3 Limitations

There are a few limitations to these studies. Although I addressed some sources of selection bias, there is still selection bias related to participation criteria for the parent study, which precludes generalization of these findings to the U.S. maternity population. CDC reported that the parent study population was better off than the general U.S. maternity population (CDC 2012). Thus, these results may be conservative estimates of the actual effects of regular pumping (compared to non-regular/non-pumping) on time to BMF (and exclusive BMF) cessation and on achievement of BMF (and exclusive BMF) intentions in the general population. I observed interaction between household income and achievement of BMF intention and estimated a strong, negative effect for the lowest household income category (<$30,000), suggesting that negative effects of pumping could be stronger for those with fewer resources. There may additional selection bias, if women were not included in these studies because they decided not to BMF due to the fact that they would return to work and anticipated obstacles to BMF while working. I decided *a priori* to use alpha=0.05 for my tests of effect measure modification. I may have detected modification from more covariates with a more liberal test.

"Regular pumping" was not defined on the questionnaire and may not have been interpreted the same way by all respondents. In addition, some questionnaires were not completed when intended, which may have resulted in possible misclassification or recall biases. Approximately 10% of women completed the month 2 questionnaire (intended at ~8.6 weeks) more than one month later (13 or more weeks after childbirth). That variation in time of month 2 questionnaire completion may have resulted in misclassified work status for some women. The survey question refers to "breastfeeding" intention but not BMF, and it is not clear if respondents interpreted the intent of the question to apply to both practices. Finally, the questionnaires assessed exclusive BMF behavior during the previous seven days, and it is assumed that the reported practice applied to the remaining days of the month. That is a common, but imperfect, way to measure exclusive BMF.

Section 5.4 Future directions

My research questions were causal in nature. I sought to add an advanced and thorough epidemiologic analysis to a mixed literature about the effects of pumping on BMF cessation and achievement of breastfeeding intentions. I used the TPB and DAG theory to design a causal analysis to investigate that effect and employed advanced epidemiological techniques to control for bias. I found that early, regular breast milk pumpers stopped BMF and exclusive BMF earlier, and were less likely to achieve their BMF and exclusive BMF intentions than non-regular/non-pumpers. My studies had several limitations, cited previously.

There are currently no post-ACA studies of the effect of pumping on BMF duration and achievement of BMF intentions in the U.S. It is important to further evaluate the effects of pump provision and workplace policies guaranteed (for some but not all) by the ACA, along with access to specialized support, on BMF and exclusive BMF durations and achievement of

intentions. Future longitudinal studies could use improved measures of pumping, return to work, and infant feeding practices in a representative U.S. population to better estimate the effects of pumping on time to BMF (and exclusive BMF) cessation and achievement of BMF (and exclusive BMF) intentions. Researchers should power their studies for their questions of interest, considering potential investigations for effect measure modification and the sample size needed. In addition, further investigation into different types of support that may assist women who regularly pump is warranted. Studies of equity in BMF practices, including pumping, could facilitate resource allocation to women in need.

Given the limitations of observational data, especially the fact that choosing to pump is not independent and is likely determined by factors that are difficult to measure, future investigators may seek an experimental design. This could be construed in workplaces that newly incorporate a facility for on-site childcare. Infant care rooms have a limited number of spaces available. If spaces for the first cohort are designated by lottery during pregnancy, consenting women could be randomized to one of two groups: regular pumpers and regular breast-feeders (feeding at breast during the workday). Both groups would be ensured adequate time and space to accomplish their feeding practices. Monthly measures of feeding practices collected prospectively until infant age of 12 months would provide information to assess the effect of regular pumping on BMF duration. Control for household income and job type would likely be necessary.

In addition, studies of the applicability of health behavior theories, and the TPB particularly, to the issue of breast milk pumping as an accessory behavior to breast milk feeding, are warranted. Pumping is a behavior that could mediate the relationship between BMF intention and practice. Studying the role of the three components of the TPB—attitude, perceived

behavioral control and social norms—with regards to pumping both before and after birth could strengthen the applicability of the TPB to questions about breastfeeding where pumping may be indicated.

Finally, studies to determine effective interventions are warranted. Further investigation of the factors affecting women's attitudes, perceived behavioral control, and social norms may provide insight for intervention. That information could be obtained through qualitative studies or perhaps through factor analysis or latent class analysis. Investigations of specific interventions could benefit from a pathways analysis, perhaps using structural equation modeling. If the literature continues to build an evidence base for causality, it will become increasingly important to design effective interventions that assist regular pumpers when and where they need them.

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APPENDIX: SUPPLEMENTAL ANALYSES

Aim 1: Additional effect estimates

	Regular pumpers (n=347)	Occasional/ non-pumpers (n=1235)
No. events	232	614
Person-weeks	11,263	45,907
Rate	2 per 100 person-weeks	1 per 100 person-weeks
Risk	0.67	0.50
Weighted rate ratio	1.46 (95% CI: 1.33 – 1.60)	-
Weighted risk ratio	1.31 (95% CI: 1.24 – 1.38)	-
Weighted risk difference	0.17 (95% CI: 0.14 – 0.21)	0
NNT	5.76	Inf.

Aim 1a: Additional effect estimates

	Regular pumpers (n=199)	Occasional/ non-pumpers (n=754)
No. events	185	644
Person-weeks	3083	12,735
Rate	6 per 100 person-weeks	5 per 100 person-weeks
Risk	0.93	0.85
Weighted rate ratio	1.12 (95% CI: 1.02 – 1.23)	-
Weighted risk ratio	1.10 (95% CI: 1.01 – 1.12)	-
Weighted risk difference	0.08 (95% CI: 0.06 – 0.11)	0
NNT	11.91	Inf.