BREASTFEEDING AND CONTRACEPTIVE USE:
ANALYSIS OF A STATEWIDE SURVEY

Alane Elizabeth Murdock

A dissertation submitted to the faculty of 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 Maternal and Child Health.

Chapel Hill
2013

Approved by:

Miriam Labbok

Carolyn Halpern

Nancy Dole

Julie Daniels

Michael Hudgens

ABSTRACT

Alane Elizabeth Murdock: Breastfeeding and Contraceptive Use: Analysis of a Statewide
Survey
(Under the direction of Miriam Labbok)

Combined estrogen/progestin contraceptive methods have a negative effect on
breastfeeding duration when compared to progestin-only methods, non-hormonal
methods or using no method. These results suggest that combined hormonal methods
should not be recommended to breastfeeding women. This is consistent with current
CDC recommendations and strengthens the evidence on which they're founded because
this study is recent, US-based, examined current contraceptive options, and controlled for
confounding using up-to-date statistical approaches. No effect of progestin-only
contraceptive use on breastfeeding duration was found when compared to either non-
hormonal methods of birth control or using no method. These results are limited by the
lack of information on the timing of initiation of use; in particular, we were not able to
distinguish early use, i.e., immediate postpartum, from later use. Consequently, these
results should not be interpreted to mean that progestin-only methods are compatible with
breastfeeding, but rather that good information about the timing of use will be necessary
to clarify the relationship between progestin-only contraceptive use and breastfeeding
outcomes.

Postpartum contraceptive use by women who initiated breastfeeding was found to
be associated with maternal age, maternal educational attainment, race/ethnicity, first
birth, infant NICU stay, and the number of breastfeeding-related hospital practices

experienced by the mother. Differences in contraception use correspond to breastfeeding rates, suggesting that the issues may be related either with common etiology or by direct effects between them. Pregnancy prevention may outweigh breastfeeding protection in a mother's use of contraception after birth. If so, accurate and available information about the impact of hormonal contraception on breastfeeding is need by these women, as well as having access to reliable and attractive contraceptive methods which are compatible with breastfeeding.

Overall, these results highlight the importance of labor and delivery practices that allow and enable immediate breastfeeding initiation for long-term breastfeeding success. These results support the importance of the Ten Steps to Successful Breastfeeding for breastfeeding duration, and suggest that greater adoption of and adherence to this standard could improve breastfeeding outcomes.

DEDICATION

To Ellie and James, my inspiration.

ACKNOWLEDGMENTS

I owe a debt of gratitude to Dr. Miriam Labbok, Dr. Carolyn Halpern and to the Department of Maternal and Child Health for seeing in me something worth the investment. By giving me the opportunity to pursue this work, you have opened a different life-path than is usually available, and I am deeply grateful for and humbled by the gift.

I am incredibly lucky to have had such an exceptional advisor. Thank you, Miriam, for sharing your expertise and wisdom and for caring about me personally. Your mentoring and friendship mean more than I can express. You are a remarkable woman not only for the caliber of your professional life and impact on the world, but also for the way you genuinely care about those around you, nurturing and supporting our goals and dreams. I will do my best to live up to the example you have set.

Thank you to my dissertation committee for supporting not only this work, but my wider life-plans. Your flexibility and hard-work have made it possible for me to pursue my dream of combining clinical and research work. I hope that my future research will be a credit to each of you for the outstanding teaching you have given me.

Dr. Hudgens, thank you especially for the many hours you spent teaching me and guiding my analysis plan. You fundamentally shaped not only this project, but me as a researcher.

Dr. Dole, I am so grateful that you agreed to serve on my committee. As I had hoped, you brought a perspective that not only improved this project, but also broadened my approach. You have given me a foundation upon which to grow my interest in psychosocial research, and your professionalism, poise, and high standards are a model to me for being a woman in science.

Dr. Daniels, thank you for your mentoring me not only through this project, but also through the training grant, and as an instructor. I am amazed and humbled by your ability to dive to the heart of an issue and identify the central challenges. Your insightfulness has enriched every conversation, one-on-one and group, that I have had the good fortune to have with you. Your have taught me to reconsider my assumptions, think critically about my plans, and have caution in my statements, in short, to be a more serious and responsible scientist.

Finally, thank you Dr. Halpern for being an outstanding teacher, a committed advocate for the PhD program in Maternal and Child Health, a wise and caring counselor, and a discerning scientist. At each stage of my progress, you have played a critical role, giving me opportunity, support, and guidance when I deeply needed it. Thank you for your warmth and kindness to me personally and for building a PhD program which has given me truly exceptional training and mentoring.

Thank you to the other faculty at UNC for their outstanding teaching, most importantly Dr. Sandra Martin, Dr. Jon Hussey, Dr. Stephanie Engel, and Dr. Whitney Robinson. A special thanks to Dr. Claudia Fernandez and Dr. Ted Mouw who are two of the best teachers I have ever had. A particular thanks to Drs. Anita and Paul Farel for encouraging my dreams and giving me the practical guidance and advice to make them a

could. Thank you to my parents Carol Rich and Larry Murdock for your love and support and to my sisters Laura Murdock and Julie Painley for being my sounding boards, cheering section, and reality check all in one.

Thank you to Clare Baxter for being a great friend to both me and my children; you make it all possible. Thank you to Elizabeth Wyngaarden, Victoria Emery, Rachel Wyngaarden and the rest of their family for being so supportive of me and reliable and caring for Ellie and James.

A special thank you to Shannon Blalock for seeing the spark inside me and fanning the embers. Your belief in me, gave me courage to embrace my dreams and turn them into reality.

Lastly, thank you to my amazing children Ellie and James Kasrawi. You have walked every step of this with me, and I am so grateful for your patience and love. Each of you is remarkable in your own, wonderful way and I am so blessed to be your mother.

TABLE OF CONTENTS

APPENDICES

LIST OF TABLES

Table

xvi

LIST OF FIGURES

Figure

SPECIFIC AIMS

Breastfeeding and Contraceptive Use: Analysis of a Statewide Survey

Breastfeeding and contraception are both important public health policy issues with personal and societal implications. Breastfeeding is known to be associated with better short and long-term health outcomes for both mother and baby. As such, improving breastfeeding initiation, exclusivity, and duration have been key goals of the Healthy People 2010 and 2020 initiatives in the United States (US). Fertility control also has important health implications, particularly in the postpartum timeframe when longer birth intervals reduce maternal mortality and morbidity and improve infant health. Furthermore, the 1994 International Conference on Population and Development in Cairo broke new ground by declaring access to voluntary family planning to be a human right, and critical for both individual and national development while noting the importance of breastfeeding for health.

The issue of hormonal contraception in the postpartum period, however, is controversial. While there are frequently reported clinical observations of reduced milk supply when hormonal methods are introduced, this is not confirmed in research on progestin-only methods. It is biologically plausible that synthetic hormones would interact with the physiological systems that support breastfeeding since progesterone and estrogen are involved in the development of the mammary gland, and its functions, including the onset of lactation. Further, the US and International sources give conflicting advice based on the same exact research literature. This project aims to

1

contribute to this conversation by exploring the causal relationship between contraceptive use and breastfeeding duration in a US population.

<u>Specific Aims</u>

<u>Aim #1:</u> To evaluate the association between demographic, social, and healthcare factors and the likelihood of weaning.

Hypothesis: Demographics, social factors, and healthcare practices experienced during labor and immediately postpartum are associated with the duration of breastfeeding.

<u>Aim #2:</u> To assess whether there is an association between demographic, social, and healthcare factors and contraceptive use in the postpartum time frame.

Hypothesis: There are associations between demographic and healthcare factors such as race/ethnicity, pregnancy wantedness, income, maternal age, education, and hospital practices, and the use of contraceptives, including the specific type of contraceptive used, in the postpartum time-period.

<u>Aim#3:</u> To assess the impact of the postpartum use of progestin-only contraceptive methods on duration of any breastfeeding.

Hypothesis: Women who use progestin-only contraception postnatally are more likely to cease breastfeeding than women who do not use contraception and women who use non-hormonal methods of contraception.

Aim #4: To assess the impact of the use of combined progestin/estrogen contraceptive methods in the postpartum period on breastfeeding success, measured as the hazard of breastfeeding cessation.

Hypothesis: Women who use combined progestin/estrogen contraception in the postpartum period are less likely to be breastfeeding at each time-point than women who do not use contraception, women who use non-hormonal methods, and women who use progestin-only contraception.

CHAPTER I: BACKGROUND AND SIGNIFICANCE

Breastfeeding in the United States

Breastfeeding is the optimum form of infant feeding according to the World

Health Organization (WHO) and the American Academy of Pediatrics (AAP). (1,2)

Research has revealed many short and long term health benefits for the baby and mother

substantiated in the research literature. (3) Exclusive breastfeeding is recommended for

the first six months of life with continued breastfeeding afterwards by the AAP and

WHO. The Healthy People 2010 initiative of the US Department of Health and Human

Services set a goal for the country of at least 75% breastfeeding initiation and at least

50% breastfeeding continuation at 6 months. (4) By 2010, 76.9% of infants had ever been

breastfed and 47.2% were nursing at six months, nearly meeting the Healthy People 2010

target. (5) However, only 16.3% were breastfeeding exclusively at six months, the

recommendation from the WHO and AAP. Healthy People 2020 set new goals for

breastfeeding over the current decade including an 81.9% initiation rate, 60.6%

continuation at six months, and 25.5% exclusive breastfeeding at six months. (6) To meet

these ambitious targets new programs and policies will be needed. This project aims to

inform that process by providing up-to-date information about breastfeeding and

contraceptive use in the United States.

Breastfeeding has been shown to have a profound effect on short and long-term

health for mother and infant. Breastfed infants have lower rates of a wide range of

illnesses including ear infections, bacterial meningitis, urinary tract infections, intestinal infections, diarrhea, and childhood cancers. (7-15) Lower rates of sudden infant death syndrome, asthma, obesity, and diabetes are also seen in children who are breastfed. (16-24) Childhood cognitive development may also be enhanced by breastfeeding. (25-27)

Mothers also experience better immediate and long-term health outcomes from breastfeeding. Women who breastfeed experience less postpartum bleeding and are less likely to have delayed uterine involution. (28) They also have lower rates of breast and ovarian cancer and fewer hip fractures and osteoporosis later in life. (29-33) Therefore, the impact of low rates of breastfeeding on long-term health for individuals and on healthcare costs as a nation is large. (34) Infant morbidity and mortality related to the low prevalence of meeting the 6-month exclusive breastfeeding recommendations of the American Academy of Pediatrics, alone, is estimated to cost the United States $13 billion annually. (35) It is well substantiated that breastfeeding has far-ranging effects on the immediate and long-term health of women and children, and a large impact on our healthcare system and economy.

However, research on breastfeeding has suffered from issues of data quality and selection bias. Study questions related to breastfeeding are often over-simplified, missing variability in behavior such as exclusivity and intensity. The ability to breastfeed could be a proxy for better health, economic, or social factors. Distinguishing the direct effect of breastfeeding from the effect of being the type of parent or family that can breastfeed has also made it difficult to isolate the impact of breastfeeding itself from the context of successful breastfeeding. Ethical and human subjects issues make many study designs

meant to address this problem, such as performing a randomized controlled trial (RCT),

inappropriate and impractical.

Family Planning

At the International Conference on Population and Development (ICPD) in Cairo,

the world community set a goal of "universal access to reproductive health" including

family planning. They identified voluntary family planning as a central component of

human rights and of national development, and highlighted the fact that family planning

is one of the most cost effective ways to combat poverty. Still, studies funded by the Bill

and Melinda Gates Foundation estimated that, as of 2009, more than 200 million women

around the world lacked access to modern methods of contraception, and predicted that

by 2050 this would increase by 40%. (36,37)

Family planning has been in the forefront of public health in the US for a century.

In its list of "10 great public health achievements of the 20th century," the CDC cited

family planning as one of the top accomplishments. They say, "…smaller families and

longer birth intervals have contributed to the better health of infants, children, and

women, and have improved the social and economic role of women." (38)

Still, the rate and number of unintended pregnancies in the US are high and there

is wide variation in prevalence by demographic factors such as race and education.

Analysis by Finer and Henshaw showed that between 1994 and 2001, the rate of

unintended pregnancy among white women was 35 per 1,000 births, while among black

women it was 98 per 1,000 and among Hispanic women, 78 per 1,000. (39) Education

also strongly predicted unintentional pregnancy, with a rate of 26 per 1,000 for women

with college degrees, and 76 per 1,000 for women without a high school degree.

Contraceptive use follows similar racial and education patterns and is thought to be a response to and a cause of these differences. (40) Thus, there is an unmet need for contraception in the US that varies by race and education, but is present to some degree for women of all demographic backgrounds. Trussell et al. estimate that the annual cost of unintended pregnancy in the US is $4.5 billion. (41)

Postpartum contraceptive use has a significant contribution to this issue. (42) Truitt et al. note, "Each year over 100 million women make decisions about beginning or resuming contraception after childbirth." A woman's decision-making concerning contraception may shift at this time as her priorities adjust with the birth of a child. New considerations and goals may cause her to reevaluate her previous choices. Further, her access to medical care might change, making contraception more or less available than before. Thus, accurate information, specific to the health and social issues at this stage is needed by women in the postpartum.

The public health implications of postpartum family planning are also important since the length of the inter-birth interval has serious implications for both maternal and infant health. Women with short birth intervals, less than six months, were found to have higher risk of maternal mortality (odds ratio (OR) 2.54; 95% confidence interval (CI) 1.22-5.38), third-trimester bleeding (OR:1.73, CI: 142-2.24), premature rupture of membranes (OR: 1.72, CI: 1.53-1.93), puerperal endometritis (OR:1.33, CI:1.22-1.45), and anemia (OR:1.30, CI: 1.18-1.43). (43) Among women with previous Cesarean deliveries, birth intervals of less than 18 months were associated with a higher risk of uterine rupture, 2.25% vs. 1.05% for intervals of 19 months or longer. (44)

While there are contraceptive methods compatible with lactation, such as barrier methods or the Lactational Amenorrhea Method (LAM), many women require or prefer to use other forms of contraception including hormonal contraception in the early postpartum time frame. (45-47) Thus, accurate information about the compatibility of specific contraceptive methods and breastfeeding is needed for these women to make informed choices about both.

Maternal Anatomy and Physiology of Breastfeeding

The breast contains the mammary gland and associated structures including muscle, nerves, blood supply and connective tissue. Milk is produced in the alveoli, structures lined with columnar epithelial cells producing the milk. Each alveola is a sac for collection of the milk and is connected to a ductule. The ductules connect to a larger duct known as the lactiferous sinus, or milk duct, which aggregates milk from many of these ductile tributaries until they reach the nipple where about seven to twenty milk ducts provide milk to the infant during suckling. (48,49)

Hormones play an important role in breast development and lactation, including mammogenesis, lactogenesis, galactopoiesis, and involution. As an organ, the mammary tissue of the breast is unusual in that it remains only partially developed into adulthood. (50) In response to the hormones of pregnancy, the mammary gland completes its development in preparation for lactation. (51) Estrogen and progesterone, two of the central mediators of the menstrual cycle, are key hormones during pregnancy; the elevated serum levels of these two hormones are necessary to maintain the pregnancy, changing over the course of pregnancy. (49) In the mammary gland, estrogen causes the

milk ducts to proliferate and differentiate while progesterone increases the number of alveoli, which are foci of milk production. (52) This proliferation of the mammary gland cells also works in concert with adrenocorticotropic hormone (ACTH), growth hormone and prolactin to increase breast size during pregnancy. (51,53) Placental lactogen influences growth of the areola, the darker skin around the nipple, and prolactin affects nipple growth. (53) Thus normal breast development during pregnancy relies on a variety of hormone signaling pathways and interactions.

Prolactin plays a central role in the mammary gland transition from pre-lactation to the onset of lactation known as lactogenesis. During pregnancy, prolactin levels rise from a pre-pregnancy level of about 10-20 ng/ml to about 200-400 ng/ml at the end of pregnancy. (54) Angiotensin II, gonadotropin-releasing hormone (GnRH) and vasopressin stimulate the anterior pituitary to release prolactin. Another hormone, prolactin, which is associated with milk production, is present throughout pregnancy. However, prolactin's effect on milk production is inhibited in three ways during pregnancy, delaying copious milk production until after birth.

First, high serum progesterone levels during pregnancy act on the alveolar cell receptors and selectively inhibit prolactin's action at this site. (55-57) The inhibitory effect is so strong that the presence of retained placental fragments after birth is enough to delay or inhibit lactation. (58) Hartmann showed that Lactogenesis II could be blocked in sheep by artificially keeping progesterone levels high after birth, suggesting that exogenous progesterones might be capable of inhibiting lactation in humans as well. (55) Progesterone is also implicated in closure of the tight junctions in the alveolar cells. The removal of progesterone after birth, coupled with the presence of glucocorticoids, closes

the tight junctions between the lactocytes and allows the milk products to be retained in the alveoli for release during suckling.

Second, high estrogen and progesterone levels act on the anterior pituitary to suppress prolactin secretion. And third, human placental lactogen (HPL), released by the placenta, competes for prolactin receptors in the alveolar cells, the milk production cells, preventing prolactin from binding to its signaling pathway. (59) This is why steroid hormones were given to women in the past, before the side effects were fully understood, as an effective means to prevent their milk from coming-in and reduce the associated engorgement of not breastfeeding. (42)

After birth, delivery of the placenta in the final stage of labor leads to a rapid decline of progesterone levels, a ten-fold decrease in the first four days postpartum. This, in turn, removes the inhibition of the alveolar cell receptors, allowing prolactin to signal milk production in these cells. It follows that the second stage of lactation, lactogenesis II, the onset of copious milk production that is colloquially known as the mother's milk 'coming-in,' occurs during this time frame, between 36 and 96 hours postpartum. (60,61) Likewise, the drop in progesterone after birth (Figure 1, as illustrated in a rat model) releases the anterior pituitary from its inhibiting effect, allowing the baseline prolactin secretion to be superimposed by a distinctive, pulsatile prolactin release which occurs 7 to 20 times a day primarily in response to feeding, with higher levels released during sleep. (62) Moreover, the drop in human placental lactogen (HPL) after delivery of the placenta releases prolactin receptors in the breast from competition by HPL, allowing prolactin to act freely on its signaling pathway.

Lactogenesis II is a function of endocrine influence, i.e., it relies on hormones released at one site acting on another site in the body through bloodstream transport. Put another way, breastfeeding establishment is hormonally driven. (64,65) It follows that milk 'coming in' is primarily a response to hormonal changes and not a response to suckling. (64,65) However, without frequent early breastfeeding and related breast stimulation, lactogenesis II is delayed. (64) Later in lactation, after four to six weeks, signaling shifts to an autocrine system, i.e., signaling by a cell that acts on the same cell. At this stage, milk production is driven by milk removal and sensory stimulation. (49,66) Thus, many women experience a change between the initiation phase of nursing and onset of galactopoiesis, the maintenance stage, by about 6 weeks, with the early weeks marked by a sense of heightened responsiveness and perhaps fragility that gives way to a more stable and resilient system somewhere between 6 and 8 weeks postpartum. This shift follows the transition from endocrine signaling to apocrine signaling.

Figure 1:

Circulating levels of progesterone, estadiol and prolactin during pregnancy in the rat
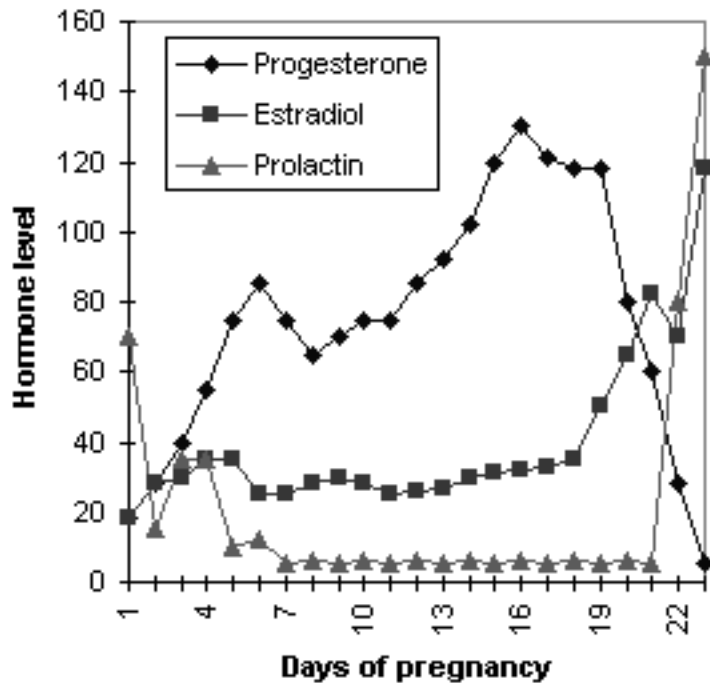
(63)

During lactation maintenance, galactopoiesis, prolactin secretion depends on suckling stimulus and regular emptying on the breast. (51) Prolactin release from the anterior pituitary is controlled by inhibition from the hypothalamus, i.e., when this inhibition is released, the anterior pituitary releases prolactin. Nipple stimulation and removal of milk from the breast inhibits the hypothalamus from releasing dopamine, a prolactin inhibitory agent. (67) The drop in dopamine allows the release of prolactin, which then leads to milk production. In the normal breastfeeding process, prolactin levels in the blood rise and fall in relation to the frequency, duration, and intensity of nipple stimulation, peaking about 45 minutes after nursing. (68) It has been shown that the neurological input that results from nipple and areolar stimulation, prolactin levels do not

rise. (69) Even midway through the first year of life, prolactin levels have been shown to increase two-fold after nursing. (70)

Many factors have been shown to be associated with prolactin levels in nursing mothers. Prolactin increases with the number and intensity of feedings, and the surges are higher when more than one child is being nursed. (54,71,72) Prolactin follows a circadian rhythm with the highest response levels seen at night. (49) Prolactin levels are higher in amenorrheic women and lower in depressed women. (70,73) Prolactin is also negatively affected by smoking. (74) Average levels decline over the duration of breastfeeding, but remains elevated as long as the mother breastfeeds. (70,71,75) The prolactin levels at 10 days postpartum average about 90 ng/ml and at 180 days are 44.3 ng/ml. (70)

Effective prolactin signaling is essential for initial milk production; without it, breastmilk production is not stimulated. (76) Therefore, it is theoretically feasible that introduction of synthetic hormones, such as those used for hormonal contraception, could interfere with the hormonal drop-off necessary for milk production, undermining breastfeeding. Since prolactin regulation is hormonally driven during breastfeeding establishment, there is heightened concern over the use of hormonal contraception in the early postpartum when endocrine pathways predominate for breastfeeding signaling. Concerns remain, however, even during galactopoiesis since inhibition of prolactin by estrogen and progesterone is still possible.

Another potential point of interaction between exogenous hormones and the breastfeeding mechanism is the prolactin receptor (PrlR) on the cell surface of lactocytes. Binding of prolactin to the PrlR receptor starts a signaling cascade, which leads to expression of genes that promote milk protein synthesis. PrlR is up-regulated in

lactocytes at birth and with lactogenesis II, increasing the number of receptors available for prolactin binding. Zuppa et al. showed that multiparous women had lower serum prolactin levels than primiparous women in the first 4 days after birth, but the infants of multiparous women received more milk. (77) They concluded that the multiparous women must have higher numbers of PrlR receptors, enabling stronger cell signaling with less prolactin. The implication is that the number of PrlR receptors not the serum prolactin level determines the milk output. This is consistent with the decrease in prolactin over time and with the finding that prolactin levels are not linked to milk yield. (70,71,78,79) If the increase in the number of prolactin receptors that occurs in the immediate postpartum is important to milk supply throughout breastfeeding, then disruption of this up-regulation, to the extent that it is unique to this time-frame, could cause lasting damage to the milk production signaling pathway. High progesterone levels during pregnancy suppress the up-regulation of prolactin receptors in lactocytes. (80) Therefore, the effect of high postnatal progesterone levels due to early use of hormonal contraception should be examined as a potential inhibitor of prolactin receptor proliferation during lactogenesis II.

Glucocorticoids also play an important role in lactogenesis II and galactopoiesis, and may interact with synthetic hormones from contraceptives. The primary glucocorticoid in humans is cortisol, which increases five-fold during pregnancy. (51,66,81) However, it is bound by corticosteroid binding globulin (CBG), which keeps the levels of bio-available cortisol low. (51,81) CBG decreases around birth, allowing an increase in serum cortisol levels at this transition point. Glucocorticoids regulate the permeability of tight junctions between lactocytes; closure of these junctions is a critical

step in lactogenesis II. (82) They also prevent involution and apoptosis, the processes of dismantling the breast tissue that occurs as a result of weaning, during on-going lactation. (83,84) Glucocorticoids also work synergistically with prolactin to enable synthesis of milk proteins by turning on transcription of milk protein genes in the lactocyte nucleus. (85-87)

Progesterone binds the glucocorticoid receptor, although with lower affinity than cortisol itself. This competitive inhibition may be the mechanism by which progesterone inhibits milk production during pregnancy. (88-90) High levels of progesterone during pregnancy out-compete cortisol for the receptor site because serum cortisol levels are held in check by CBG, thus inhibiting cortisol's milk production effects. Around birth, CBG levels fall, releasing cortisol and making higher concentrations available in the blood. With the dramatic decline of serum progesterone after birth, the balance of competition for the glucocorticoid receptor site shifts in favor of cortisol, and milk production is released. Exogenous progesterone, as from contraception, could compete with cortisol for these receptor sites at any time during lactogenesis II or galactopoiesis, inhibiting milk production.

Estrogen, too, has been shown to impact lactation; in humans it is considered a potent inhibitor of milk production based on clinical reports. (91-95) In some animal models, estradiol increases milk production by reducing inhibition of prolactin production in the anterior pituitary. In rats, this is accomplished by reducing the number of prolactin receptors on the lactotroph. With fewer prolactin receptors, the lactotroph's response to circulating prolactin is muted allowing it to continue producing prolactin in spite of circulating prolactin levels. (96) It is not known whether this is also true at the

15

level of the anterior pituitary in humans. However, the literature suggests that in at least some women estrogen can suppress milk production. Moreover, in the first days after birth, the blood brain barrier in infants is partially open, theoretically allowing synthetic hormones that pass through the mother's milk to expose the infant brain with exogenous hormones to unknown effect. (97)

Based on the clinical observations and the biological plausibility of the underlying biological processes, it is reasonable to question what effect hormonal contraception might have on breastfeeding. In *The Textbook of Human Lactation*, Hale and Hartman say, "In all species…progesterone withdrawal is essential for initiation of lactation." (p. 99) (48) What then happens if synthetic progesterone in the form of hormonal contraceptives is given to breastfeeding women, and is there a critical window during which these exogenous agents alter the course of breastfeeding, and another window in which there is no impact? Likewise, how do exogenous estrogens affect lactation success, and do all forms of contraception that include estrogen have the same effect on breastfeeding?

WHO AND CDC GUIDELINES FOR CONTRACEPTIVE USE

The WHO addressed the question of contraceptive use during lactation when it produced the first Medical Eligibility Criteria (MEC) for Contraceptive Use in 1996. (98) The latest WHO MEC, the fourth edition, was released in 2009 and includes more than 1800 specific recommendations for 18 contraceptive methods and more than 160 medical conditions. (99,100) From the start, the WHO partnered with the Division of Reproductive Health of the US Centers for Disease Control and Prevention (CDC) to

identify and evaluate the available literature and synthesize the data to be used as the foundation of the guidelines. An on-going system to identify new, relevant research called Continuous Identification of Research Evidence (CIRE) was developed by the WHO, CDC and Johns Hopkins University in 2002, and allows the guidelines to be updated as new information becomes available. Until 2010, the US never formally adapted the WHO MEC for use in the United States, rather leaving it to training programs, courses, and organizations to establish their own standards based on the international consensus.

In the CDC's adaptation of the 2009 WHO MEC, the same 1-4 safety rating given in the WHO guidelines are used, adjusting only a small number of recommendations in light of US-specific conditions or new evidence that had become available after the WHO developed its guidelines. In June of 2008, the CDC convened a panel of 8 family planning experts to select areas of the WHO MEC for adaptation to the US, preserving the WHO guidance, "…except when a compelling reason existed for adaptation…" (99) In addition to removing sections for practices and drugs not used in the US, six topics were chosen for consideration for adaptation to the US setting, including contraception during lactation. Of the approximately 23 adaptations made to the WHO MEC, eight were for contraceptive use during lactation. The WHO and CDC guidelines were based on the same scientific literature, but came to different conclusions, with the CDC consistently down-grading the safety guidelines for hormonal contraceptive use by lactating women (Appendix C). Notably, seven of the eight changes shifted the guidelines from category 3 to category 2, i.e., from, "3= A condition for which the theoretical or proven risks usually outweigh the advantages of using the method," to, "2=A condition

for which the advantages of using the method generally outweigh the theoretical or proven risks." (99,100)

Soon after release of the CDC MEC, the WHO released revised recommendations based on a literature review that revealed an increased risk of venous thromboembolism in women who used combined hormonal contraception in the first 42 days postpartum. The WHO's update applied to non-breastfeeding women only since the recommendations for breastfeeding women already advised against use of these methods in this time period. This update from the WHO led the CDC to update the US MEC, matching the WHO guidance on combined hormonal contraception in the early postpartum for all women. (101) Then in June 2013, the CDC released an updated MEC clarifying that use of Progestin-only contraception in the immediate postpartum period is acceptable for breastfeeding women. (102)

Observation from clinical practice, however, suggests that use of contraceptives in accordance with these guidelines will interfere with lactation. Dr. Ruth Lawrence, author of the seminal textbook on lactation, sums up this perspective in a recent editorial, "The breastfeeding community has struggled with the question of early use of medroxyprogesterone (Depo-Provera, Pfizer, New York, NY) and the suppression of lactation. Simple principles of lactation would suggest the use of medroxyprogesterone is detrimental when it is the physiologic decrease in progesterone with the passage of the placenta that initiates lactation…The question remains to be solved in the clinical laboratory and the peer-reviewed literature." (p 1)(103) However, these clinical observations have not been validated in the scientific literature, nor could they be, since studies have not been carried out in a US context to address this controversy. Thus, the

issue of whether and when hormonal contraceptives are compatible with lactation has still not reached a consensus between the breastfeeding and family planning communities.

This project hopes to further that conversation by providing additional evidence on the associations between postpartum contraceptive use and breastfeeding duration and analysis of a causal link between progestin-only methods or combined estrogen/progestin methods and breastfeeding duration.

Summary of the Current Literature on Hormonal Contraceptive Use and Lactation

To establish the current state of knowledge on hormonal contraception and breastfeeding, relevant articles from several sources were gathered. First, since this project is largely a response to the current WHO and US guidelines for contraceptive use during lactation, any study in humans that was used as a basis for the WHO MEC and US MEC was included. (98,99) In additional, papers reviewed in each of three current review articles were included. (104-107) Lastly, to ensure that this document is up to date, specific recent papers not mentioned elsewhere were included. The results are summarized by type of hormonal contraceptive in Appendices 1 and 2. Single studies often evaluated more than one type of hormonal contraception, and therefore, are represented in every section for which they are relevant, creating some redundancy between sections. A summary and evaluation of the findings follow.

Combined Hormonal Contraception (CHC)

The CDC identified 10 relevant papers addressing combined hormonal

contraception and breastfeeding in its review of literature for the WHO MEC. However,

in the documentation in the MEC they write:

> "Evidence: Clinical studies demonstrate conflicting results regarding
> effects on milk volume in women exposed to COCs during lactation;
> however, no consistent effects on infant weight have been reported.(133-
> 142) Adverse health outcomes or manifestations of exogenous estrogen in
> infants exposed to combined contraceptives through breast milk have not
> been demonstrated; however, studies have been inadequately designed to
> determine whether a risk of either serious or subtle long-term effects
> exists." (98)

In spite of the potential negative effects on breastfeeding, a report from 1994 showed that

many breastfeeding mothers in that era strongly preferred to use combined hormonal

contraceptives. (108) It is not known whether today's mothers have the same preference,

and given the greater public awareness of the benefits of breastfeeding for both mother

and baby, extrapolation from 1994 is limited. However, many of the reasons cited by

mothers in 1994 are still relevant today: familiarity with the method, beneficial effects for

menstrual cycling, and control of bleeding. CHCs, then, remain an important part of the

contraceptive options still considered by breastfeeding mothers. In their review of the 10

articles used for the WHO and CDC MECs, Kapp and Curtis say, "the body of evidence

pertaining to the use of combined contraception during lactation is limited and largely of

poor methodological quality and includes only oral formulations." (p 12) (104)

The WHO identified four studies that used full or partial randomization.

According to Kapp and Curtis, two of these were of poor quality and the other two, which

were only fair quality, had conflicting results. The RCTs done by Kaern and by Miller and Hughes were both deemed to be poor quality because they failed to show how they randomized their treatment. Miller and Hughes saw marked differences in breastfeeding duration between COC users and non-users, as well as, lower infant weight gain and a need for supplemental calories around four to five weeks in this group. However, the paper did not specify important information needed to evaluate the findings such as how the subjects were randomized, what statistical tests and values were used, and blinding and allocation techniques which together make their results unreliable. Kaern also found a statistically significant difference in supplementation among women who received COCs from one to eight days postpartum, but contrary to their findings, concluded that lactation was not inhibited. They followed their subjects only until discharge at eight days postpartum, however, and provided very limited study details and statistics, again making it difficult to draw reliable conclusions from their work.

The results of the study by Guiloff et al. are questionable because they used the woman's previous breastfeeding duration, recalled at the time of the referent breastfeeding experience and contraceptive intervention, as the control for her current duration. Work by Zuppa et al. on prolactin levels provides one possible explanation as to why this is a poor control (77); multiparous women were found to have lower prolactin levels in the first days postpartum, but to have more milk than primiparous women. Another major problem is recall bias in women's report of past breastfeeding duration. Other studies have found longer breastfeeding durations with subsequent children; this means that the Guiloff study found similar breastfeeding durations between groups for which different durations were expected.

Two studies from the same research group in Chile were found to be of fair quality by Kapp and Curtis. (109,110) Croxatto and Diaz used a partially randomized study design to examine COC use beginning at 30 days postpartum. In both cases, they found that the COC group had significantly higher rates of breastfeeding cessation and lower infant weight than the non-hormonal control group. However, the women in their studies were allowed to choose whether to receive treatment, that is, the control group was selected from only those women who were willing to use lactation for pregnancy prevention, but the treatment group included women who were not willing to rely on lactation for contraception. Since the study subjects were not truly randomized, the treatment and control groups could have been different on relevant covariates, but no adjustment was made for confounding.

An RCT carried out by the WHO in Hungary and Thailand had a strong multi-center design, but failed to address confounding. (111) They found differences in milk volume and mineral and fat content for COC users, but no difference in infant weight, length, rate of growth or illness. They also saw no effect on breastfeeding cessation. However, they did not address supplementation, and in settings where breastfeeding is normative, supplementation may be the more logical relevant place to observe impacts on breastfeeding. Since this study, with a strong RCT design, found differences in the quantity and quality of the milk, it substantiates that COC use can affect breastmilk. The lack of effect on infant growth may be more context specific, and it may not be the best measure of breastfeeding success since infants supplemented with formula may not grow differently. Without information on supplementation, it is impossible to know whether

the intensity of breastfeeding is affected or whether supplementation is normative in these settings.

A study carried out at a US Military hospital in Germany is perhaps most interesting not for its results, but for the commentary by the author. (92) He says, "There were some apparently well-motivated patients, who seemed to have lactation suppression from the pills and were unable to breast feed more than from 1 to 5 weeks." (p 102) Among breastfeeding women, 54% of the COC group was still nursing at 6 weeks, compared to 59% of the control group. Likewise, 25% of COC users cited decreased milk supply as their reason for stopping compared to 13% of the control group. In spite of this, the author concludes that there was no suppression of lactation from COCs. Similarly, a retrospective cohort study from Sweden reported no detrimental effects of COC use while breastfeeding because they found no differences in number of serious illnesses or in school performance up to age 8 between COC users and non-hormonal controls. (112) However they did find that the mean duration of breastfeeding was shorter in the COC group than controls, 3.7 vs. 4.6 months. Lastly, another study based in Chile found lower rates of exclusive breastfeeding with COC use, and lower infant weight gain at 4 months, a time when many dyads experience a need for increased milk supply. (113) However, like the other studies discussed here, no adjustment was made for confounding, making the results difficult to interpret.

Taken together, the work to date on COCs and breastfeeding suggests a negative effect on milk supply, but the literature is impaired by study design and lack of adjustment for confounding. All of the non-RCT studies failed to address confounding in any way. Since the RCTs rely on robust randomization to address this issue, the lack of

clarity about methods and success in the randomization process calls into question

whether confounding can be ruled out in these studies. Indeed, in several cases, subjects

were allowed to *de facto* pick their treatment by choosing their mode of hormone

delivery. To the extent that differences between women correlate with their choice of

mode of contraceptive delivery, the RCTs would be compromised. All in all, there is still

a need for well-designed research on the topic.

Progestin-only Contraception (POC)

There are considerably more studies available on the effects of progestin-only

contraception (POC) on breastfeeding, perhaps reflecting the belief that POCs are the

preferred type of contraception to use while breastfeeding and the fact that a variety of

methods of POC are available, utilizing different active ingredients and delivery systems.

The WHO MEC is based on 36 studies in humans; the review by Kapp, Curtis, and

Nanda includes an additional 5 human studies included in this summary of the literature,

and several additional papers specifically suggested for inclusion have been incorporated

as well.

Progestin Vaginal Ring (PVR): Five articles that explored the impact of using a

progestin releasing vaginal ring while breastfeeding were identified and reviewed. (114-

118) All of the studies involved initiation of use between four and nine weeks

postpartum. All five of the studies found use of the PVR to be compatible with

breastfeeding. (118) Two found that PVR users had better breastfeeding outcomes than

users of non-hormonal IUDs. However, issues common to the topic area were also a

problem in this part of the literature, namely, inadequate handling of confounding and a failure to standardize treatment. The work by Diaz et al. used a historical control in which a women's report of previous breastfeeding outcomes were used as the control group for her outcome in the study. This is problematic due to recall bias in reporting of earlier breastfeeding experiences, and because key breastfeeding outcomes generally improve with parity. (114) The multi-center work by Sivin et al. showed marked differences between centers at baseline, but did not address this potential confounding in their analysis. (118) Shaaban et al. did not report their baseline characteristics, and also did not attempt to control for confounding in their analysis. (117) The two papers by Massai et al. had limitations in their design. The 1999 study had a very large window postpartum for initiation of use, five to nine weeks, and also might have included repeat reporting. (115) The 2005 study compared different regimens of treatment, but lacked a non-hormonal control. (116) Taken as a group, the findings of these five papers show a consistent trend towards compatibility of use for initiation during breastfeeding in the second and third months postpartum. However, there are significant concerns about the reliability of the findings.

Progestin-releasing IUD: The recommendations given in the WHO MEC for postpartum use of intrauterine devices (IUD) for contraception for both breastfeeding and non-breastfeeding women are based on 25 papers on IUD use in the postpartum window. (98,101,119) None of these papers focus on breastfeeding as an outcome, rather they are primarily concerned with the safest time for insertion to avoid expulsion, infection, and uterine perforation. While these issues are important for the mother's health and for her

contraceptive efficacy, they do not inform a conversation about the effect of exogenous hormones on lactation initiation and success. Indeed, while the WHO does not recommend insertion of a progesterone releasing IUD until at least 4 weeks postpartum, they do not cite any papers to substantiate this decision. In their adaptation of the WHO guidelines, the CDC classifies insertion of the levonorgestrel-releasing IUD, known by the brand name Mirena, immediately after delivery of the placenta as being acceptable (level 2) for breastfeeding women. They too cite no papers on which they based this recommendation. In addition to concerns about the unknown effect of exogenous hormones in the immediate postpartum time period, are concerns about whether the stronger uterine contractions experienced by breastfeeding women could cause expulsion of the device.

A search on PubMed using similar search words as employed by the WHO in their review of the relevant literature on combined hormonal contraception and progestin-only contraception identified three papers with primary research on hormone containing IUDs and breastfeeding. Shaamash et al. executed a randomized controlled trial (RCT) comparing the Mirena IUD and Copper T (Cu T380A) IUDs and found no difference between the two groups in their exclusivity or continuation rates, nor the number of feeds per day. (120) However, a review of their results across four time-points in the first year shows that, in every instance, the Mirena IUD had worse breastfeeding results than the Copper T, a picture that would be consistent with a reduced milk supply. For example, the Mirena group had more episodes of breastfeeding at each time point, and higher rates of partial breastfeeding at three and six months, a time frame when exclusive nursing is recommended. The Mirena group had higher weaning rates and lower cumulative

continuation rates throughout the year. What makes these trends worrying in spite of their

lack of statistical significance is that the breastfeeding rate in this population far exceeds

the US breastfeeding rate and population health is dependent on breastfeeding for both

infant and maternal health. Sixty percent to 80% of women in this part of Egypt are

nursing at 1-year, compared to just 25.5% in the US. (5,121) Indication of challenges in a

population where breastfeeding is normative, even weak indications, might be a sign of

issues that would have a far greater impact on breastfeeding outcomes and the related

ramifications for population health in the US setting. For example, if Mirena put

downward pressure on the milk production pathways, the result of this challenge would

be slight in a population with frequent nursing, little mother-baby separation, and strong

social support for breastfeeding continuation. Whereas the same downward pressure

could have a large impact in a setting where increasing the frequency of feeding is neither

practical nor socially supported. Thus, the population differences between nursing

behavior in Egypt and the US make generalizing the results of the Shaamash et al. RCT

to the US setting difficult.

The study by Chen et al. in Pittsburgh is more readily generalizable to the US

setting. In their RCT of Mirena insertion timing, they compared postplacental insertion,

i.e., within 10 minutes of delivery of the placenta, to delayed insertion, i.e., six to eight

weeks postpartum. They showed effective randomization with the two groups having

similar social and demographic characteristics, and slightly higher breastfeeding initiation

rates among the postplacental group, 64.0% vs. 58.7%. The median duration of

breastfeeding however, was significantly different, 5 weeks for the postplacental group

(range 0.5-27 weeks) and 8.5 weeks for the delayed insertion group (range 0.1-43 weeks).

More women in the delayed group continued to breastfeed at 6-8 weeks, three months, and six months postpartum, and these differences were statistically significant at 6 months (p=0.02). These trends held when only those who initiated breastfeeding were analyzed and when only primiparous women were included. These results suggest that hormonal exposure in the immediate postpartum has negative effects of breastfeeding when compared to later exposure. Their study was not designed to reveal whether hormonal exposure in general is deleterious to breastfeeding, though comparison between the groups gives some indication of the hormonal /non-hormonal effects in this time-frame. Overall the findings are consistent with the understanding that progesterone signaling in the immediate postpartum can be disrupted by exogenous synthetic hormone exposure, negatively impacting breastfeeding.

Heikkilä and Luukainen looked at hormonal vs. non-hormonal IUD use with consistent insertion times. (122) They found that in the immediate months after insertion, IUDs with 30 μg /day of levonorgesterel negatively impacted breastfeeding relative to use of a non-hormonal IUD. Those in the hormonal group discontinued breastfeeding at significantly higher rates, 44% vs. 21% at 75 days post-insertion, and also introduced substitute foods sooner, 3.4 months vs. 3.9. Their work is consistent with concerns about the effect of synthetic progesterone exposure, but cannot be directly generalized to the current US method, Mirena, which has 20 μg /day of levonorgesterel. As with the Egyptian study, the location and date of the work also make direct comparisons difficult.

Taken together, however, these studies suggest that exogenous progestins can impact breastfeeding, especially at the margins, i.e., when breastfeeding cessation is already likely. Not only is more work needed on this topic, but these studies also suggest

that properly controlling for factors which challenge breastfeeding continuation will be important.

Progestin-releasing Implants: Twenty articles were identified that discussed the use of a subdermal progestin releasing implant, but only one of these studies was conducted in the US. Two were randomized controlled trials and the rest were all cohort studies. (114,117,123-140) Among studies with insertion times around one month postpartum or later, most studies found no differences in breastfeeding or infant growth outcomes. Two articles noted a statistically significant difference in infant weight at 3 or 4 months that disappeared at later time-points. (130,135) This time period is often marked by an increased demand for milk, and these findings might suggest that the response in milk production to higher infant demand is sluggish in women using progestin-releasing implants. Schiappacasse et al. found higher rates of respiratory infections, skin conditions, and eye infections among infants of Norplant users compared to non-hormonal IUD users, but Kapp et al. suggest in their review that the high urban pollution at the study site in Chile may limit the relevance of this finding for US settings. (105,134)

Most studies evaluated later insertion, i.e., around or after the first month postpartum. However, three articles specifically looked at timing of insertion. (123-125) Brito et al. saw no effect of early insertion, but in their DMPA control group, use was initiated at six weeks, introducing an additional dimension that makes their findings difficult to interpret. (124) The other two papers both compared early and later insertion of the same implant, with an additional non-hormonal control group in one of these papers; their results conflicted, however. Seth et al. found statistically significant

29

differences in supplementation rates at three months relative to a non-hormonal control group, but their sample was small and they did not attempt to control for differences in group characteristics. (123) Gurtcheff, found no difference in onset of lactogenesis II between early and later insertion, and also found similar breastfeeding failure rates in both arms of the study. (125) Thus, additional work is still needed to clarify the impact of early insertion relative to later insertion or use of non-hormonal methods.

These twenty studies shared a number of problems in their methodology that add difficulty to the interpretation of their results. Many did not attempt to adjust for confounding in any way. This is particularly problematic since only two studies were randomized and the rest had some degree of self-selection of treatment by study subjects. Several studies reported very high loss to follow-up or discontinuation rates. Lastly, the Copper IUD was used as a control for most studies. Some findings suggest that outcomes for Copper IUD users may differ from those who use barrier or surgical methods or no method of contraception. If this is so, these studies might have used an inappropriate control group that masked the real impact of progestin releasing implants. Still, the consistency of the results across the later insertion date studies gives weight to the finding that use of progesterone releasing implants inserted in the later postpartum are compatible with successful breastfeeding.

Finally, only one study was conducted in the US, the others were undertaken primarily in Chile, Egypt, Thailand and India. Differences in breastfeeding norms among these countries and the US highlight a need for US-based research. For instance, if the lower infant weight gain seen around 3 and 4 months in several studies indicates that use of an implant results in a diminished response to infant demand, then in settings where

pressure on the supply and demand feedback system is high, there would be more vulnerability to breastfeeding problems. For instance, in the US where there is large social pressure to nurse less frequently, and where separation of mother and baby is the norm, a diminished response to infant demand could have a much larger impact on breastfeeding exclusivity and duration than in settings where frequent nursing is common.

Injectables, DMPA and NET-EN: Fourteen articles on injectable forms of progestin-only contraception were identified, covering a wide array of locations including two in the US. Ten studies were designed to elucidate differences between types of contraceptives, one study looked specifically at timing, two looked at both timing and type, and one was purely observational. Of the 'type' studies, three compared administration of an injectable at or before hospital discharge to a placebo or use of a non-hormonal method. The results of these studies were mixed; one found a trend towards longer breastfeeding duration with DMPA use compared to use of a non-hormonal method (10.14 vs. 6.57 weeks, p=0.19), but was not sufficiently powered to distinguish a difference between the two groups. (141) Another reported statistically significant differences in breastfeeding cessation at four weeks, but no difference at two or six weeks. (142) The third found continuation rates at 12 weeks postpartum of 68% and 74% for NET-EN and placebo, respectively, but said that the results were not significant at either six or twelve weeks. (143) The first and third both suffered from samples sizes too small to power their studies, and the first two failed to address confounding in any way.

Three studies looked specifically at timing of use, comparing early application to later. (124,144,145) Unfortunately two of these were designed such that their results are highly questionable. Guiloff et al. used historical controls, comparing the current breastfeeding outcomes to recalled outcomes from a previous infant. Not only is recall bias a major challenge to their results, but prior breastfeeding experience is also known to be associated with current breastfeeding success, which means that historical controls may introduce bias. Brito et al. compared insertion of an etonogestrel implant in the first two days postpartum with DMPA administration at 6 weeks. Though they report no difference in exclusive breastfeeding rates at 12 weeks, there is no way to distinguish the timing effect from the method effect, which could spuriously make both appear acceptable even if both negatively impact breastfeeding. (124) In the final study, Karim et al. primarily evaluated milk composition and infant growth outcomes between several methods used early and late. However, breastfeeding outcomes, specifically duration, were only assessed anecdotally, making the study nearly worthless for evaluating impacts on lactation, per se, since infant growth outcomes can be influenced by supplementation. (145)

Finally, seven studies explored the effect of late initiation of injectable progesterone-only contraception. The timing of onset of use varied from five to seven weeks in the earliest study to two to four months in the latest. These studies found either no difference in breastfeeding outcomes or a positive impact. A study in Chile found that DMPA users were the most likely to nurse past 20 months, and another in Chile found that DMPA users breastfed on average for 21 months compared to 13 for non-hormonal controls. (146,147) However, both of these projects as well as two others made no effort

to adjust for confounding. (93,111,146,147) Of the other three, one simply failed to report baseline characteristics and methods and another grouped DMPA and POP use together. (117,148) The final project, a WHO multi-center cohort study, found no differences in breastfeeding outcomes across the study sites, but identified large differences in breastfeeding outcomes at individual sites. (137,138)

Overall, the literature on use of injectable progestin-only contraception during breastfeeding is disappointing. While a relatively large number of studies have been done, issues with study design and methodology call the results of every one into question. New studies are needed which utilize more robust techniques to address confounding. Furthermore, thoughtful measures and comparisons need to be made in order to distinguish the effects of timing from the impact of type of contraception.

Progestin-only Pill (POP), aka Mini-pill: Fifteen articles on use of Progestin-only pills (POP) were included in this summary. Five studies examined initiation of use within a week of delivery, and eight looked at late onset of use, ranging from one to four months postpartum. No studies compared timing of initiation. Two additional studies looked at Chlormadinone derivatives. However, both addressed breastfeeding in ways that make them not informative for this topic. (149,150)

Among early onset use, two studies reported a positive effect of POP use, two reported no effect, and one reported a negative effect. Kamal et al. administered POP contraception at 2 days postpartum and followed-up for 14 days. (151) They noted that the POP group initiated breastfeeding at three days versus five days for controls. However, given the unclear terminology, it is unclear whether this truly reflects a

difference in lactation or whether it is indicative of a behavioral difference. This study

was also very small and subjects self-selected their treatment category. McCann reported

that POP users began supplementation later than non-hormonal controls, 5.4 vs. 4.6

months, respectively, but the study had a very high rate of loss to follow-up (i.e., 55% at

nine months) making their finding questionable. (152) Giner et al. saw no effect on

breastfeeding initiation, milk volume, or infant growth, but also had a small sample,

twenty women, and did not describe their methods clearly. (153) A Scottish cohort found

no significant differences in breastfeeding rates at three and six months, but allowed the

subjects to self-select their treatment and did not control for confounding. (154) A

prospective cohort study done in Los Angeles, California reported that 76.7 % of POP

users were still breastfeeding at four weeks compared to 83.1% of users of non-hormonal

methods (p=0.022). (142) However, they observed no difference at two and six weeks.

Moreover, they grouped DMPA, POP and implant users together in this analysis, and

additionally made no attempt to adjust for confounding although the treatment groups

differed significantly on mother's age, mode of delivery, and prior breastfeeding

experience.

Among the late-onset studies, four identified no differences between POP and

control groups, one had mixed results, two found positive effects. An additional project

from India looked primarily at infant hormone exposure, and is therefore not directly

related to the impact on breastfeeding per se. (136) Among the four articles that identified

no effects on breastfeeding outcomes with POP use, all began use at six weeks or later.

They also all had methodological shortcomings around failing to address confounding.

One study whose results were reported in two different papers, made no attempt to

address confounding, although loss to follow up was high in some groups. (93,111) Another used historical controls, which, as discussed above, are not appropriate for breastfeeding outcomes. (114) The other article, a WHO multi-center cohort study, found that the breastfeeding outcomes varied greatly by site, although the overall results showed no effect of POPs. (137,138) Work by Guiloff et al, which showed no effect of one synthetic progesterone on median duration of breastfeeding and a sizable impact from a different synthetic progesterone, was also undermined by the use of historic controls. (144)

Finally, two studies of late onset POP (28-56 days use showed positive effects. In an Icelandic cohort, 78% of POP users were breastfeeding seven months after initiating use between days 28 and 56 postpartum compared with just 59% of IUD users. (155) This group had a relatively long follow-up, two and a half years, but small sample size, 42 and 41 in the treatment groups, respectively. In Chile, Zacharias et al. found that the median duration of breastfeeding for IUD, DMPA and POP users, who began use between three and six weeks postpartum, was 19 months, versus 17 months for those using no method of contraception, but breastfeeding exclusively. However, it is difficult to draw conclusions since three methods were grouped together. Moreover, they too did not adjust for confounding. (147)

Across the literature examining POP, then, the results are mixed. Interpretation is difficult due to small sample sizes, poor study design, and failure to address confounding. In spite of the body of literature already available on this topic, then, new work is needed to elucidate the impact of POP use on breastfeeding outcomes and, if appropriate, the optimal timing of initiation.

Factors Associated with Breastfeeding Outcomes

Breastfeeding is a biological, behavioral, and social process and as a consequence a large number of factors are associated with breastfeeding outcomes. A literature search was conducted using PubMed with the search terms breastfeeding, breastfeed, predictor, and determinant.. Further searches for breastfeeding and postpartum depression, race, obesity, nativity, income, SES, parity, WIC, and pregnancy intention were also conducted.

Demographic Factors: A variety of demographic factors have consistently been reported to be associated with breastfeeding outcomes. Many studies report that older mothers breastfeed longer than younger mothers including large cross-sectional studies, such as the work of McDonald, et al. that included over 90,000 infants. (156,157)Increasing parity has also been found to be associated with breastfeeding success, with primiparous women demonstrating less breastfeeding success. (158,159) The mother's educational attainment is also widely reported to be associated with breastfeeding rates. (160-162) For example, a medical records review carried out in San Francisco, California, found statistically significant differences in breastfeeding initiation and continuation at 1 month postpartum by educational level. (156) A large prospective cohort study associated with an RCT of home visits found that women with college degrees are more likely to initiate and continue breastfeeding than those with 12 or fewer years of education. (163) In

summary, the literature is consistent in reporting that maternal age, parity, and education are associated with breastfeeding outcomes.

Association of breastfeeding initiation and rates of continuation with race/ethnicity have also been widely reported and consistently show higher initiation among Whites and Hispanics, with lower initiation and continuation among Blacks. Large cross-sectional surveys, such as the Pregnancy Risk Assessment Monitoring System (PRAMS) and the National Survey of Children's Health, which included over 33,000 children, report that Black women have the lowest breastfeeding rates of any racial/ethnic group. (160,164,165) Singh et al. found that differences in breastfeeding by race/ethnicity were greater for duration than for initiation. (160) Gill's systematic review of the literature for the years 1998-2008 found that Hispanic mothers generally have the highest initiation and early breastfeeding rates, but often do not breastfeed exclusively. (166) Fewer studies report on breastfeeding rates for Asian Americans, however Soni et al. carried a review of electronic medical records and found that Asians had the highest rates of exclusive breastfeeding. (167)This study only had 100 subjects, but Taveras et al. found similar results in a sample of 1,163 mothers. (163) The CDC analysis of the breastfeeding data found in the National Immunization Survey, confirms these associations over several years. The ongoing gap between racial groups is of great concern as the Black population is lagging behind in the overall increasing rates of initiation, exclusivity and duration.

Associations between breastfeeding outcomes and marital or partnership status have been found as well. Geraghty et al. carried out a study in partnership with the Cincinnati Children's Research Human Milk Bank in which they found that marital status

was associated with breastfeeding duration.(158) However, the association may be more nuanced than that. Singh et al. found that children in 2-parent step-families were less likely to be breastfed, while Pippins et al. found that both married women and those living with her partner were more likely to breastfeed. (156,160) Overall, partnership status is commonly found to be a significant factor in breastfeeding outcomes.

Parental immigrant status, or nativity, has also been found to be associated with breastfeeding duration and may modify the relationship between SES and breastfeeding outcomes. In a large national sample, Singh et al. found that children born to immigrants were the most likely to be breastfed until 6- and 12-months. (160) The association was more significant among lower SES households than higher SES households. While nativity is not a commonly used demographic variable in the breastfeeding literature, these findings suggest that it could be an important issue, especially because the breastfeeding-supportive association found at lower levels of SES runs counter to other breastfeeding trends such as maternal education and family income.

Regional differences in breastfeeding rates across the US have also been reported by the CDC and other national databases. (5,161,168) In these large national surveys, Western states breastfeed at the highest rates, followed by the Northeast, Midwest, and finally the South. Interestingly, Belanoff et al. found that breastfeeding duration varied more between states for Blacks and Hispanics than for Whites. (164) Their work, using data from the 2007 National Survey of Children's Health, suggests that region may be a more important factor in breastfeeding outcomes for racial and ethnic minorities than for whites. Living in rural areas has also been associated with lower initiation and shorter duration of breastfeeding. (160,161) In a mixed methods study of breastfeeding in rural

communities, Flower et al. reported much lower rates of breastfeeding initiation and continuation at 6 months for rural communities in Pennsylvania and North Carolina than the national average. In their ethnographic study of North Carolina families, they found that many women in these areas never even consider breastfeeding. Thus, on a national scale and a state scale, region has been shown to be associated with breastfeeding outcomes.

Economic Factors: A number of large, national studies including those by Singh et al. and McDonald et al. (157,160) have found that higher-income women are more likely to breastfeed than their lower income counterparts. However, in a study of medical records Pippins et al. found that, among the very poor, not having enough money for food was associated with breastfeeding. (156) This subtlety may be lost in studies that ask fewer specific questions about economic status. Those that group these factors into socio-economic status (SES) consistently report an association between lower SES and worse breastfeeding outcomes. (160)

Even when controlling for SES and/or household income, maternal employment is consistently found to be associated with shorter breastfeeding durations. Maternal employment at 2-months and full-time employment were associated with breastfeeding discontinuation by 6-months in studies by Flower et al. and Chapman et al. (161,169) This effect may vary by workplace; in their prospective cohort study of 1,163 mothers, Taveras et al. found lower rates of breastfeeding continuation at 12-weeks for those who returned to work, with lower rates for those who reported having problems with breastfeeding at work or school. (163) In a Canadian population, Kehler and Tough

39

found that not only was working full-time was associated with a higher risk for breastfeeding discontinuation, but intending to return to work within the first year after birth was as well. (162)

Health Factors: The mother's history of health and health behavior may be predictive of breastfeeding success. Mothers who smoke have consistently been shown to be less likely to breastfeed and to do so exclusively. (156,157,160) Many studies also find a negative association between maternal obesity and breastfeeding. (162,170-173) Li et al. also found that women who were obese before pregnancy breastfed two week less on average than mothers who were not obese before pregnancy. (173) However, differences in this association by race have been reported; Kugyelka et al. found that while obese Hispanic mothers breastfed at lower rates than non-obese Hispanic mothers, there was no association between obesity and breastfeeding continuation for black mothers, a result consistent with several other studies(165,169,174) While obesity has been suggested as affecting breastfeeding through health-related mechanisms, the racial differences in this association suggest that social or cultural influences may also be involved.

Gestational weight gain has also been found to be negatively associated with breastfeeding duration. Li et al. analyzed outcomes for over 124,000 mother-baby pairs from the Pediatric Nutrition Surveillance System (PedNSS) and the Pregnancy Nutrition Surveillance System (PNSS) and found that both pre-pregnant body mass index (BMI) and gestational weight gain were associated with shorter breastfeeding duration. (173) They found that women who gained either more or less than the recommended amount of weight during pregnancy had 1-week shorter breastfeeding durations than

those who gained the recommended amount. In contrast, Hilson et al. found that the association held only for women who were overweight or obese before pregnancy. (175) Obesity, pre-pregnancy BMI, and gestational weight gain are all active areas of research with interesting, but as yet, unresolved findings.

Reproductive Health: A women's reproductive health has also been found to be associated with breastfeeding success. Looking at all hospital births in a year in Ontario, Canada, McDonald et al. found that women with no pregnancy complications and who did not use reproductive assistance have higher rates of exclusively breastfeeding at hospital discharge. (157) Their work used a very large database, over 92,000 infants, but generalizing to the US setting is limited by differences in access to healthcare, standard of care, and maternity leave policies to name just a few factors. This same study showed that mothers with twins were less likely to breastfeed than women with singleton births, a finding consistently reported in the literature. Flower et al. reported that older gestational age is associated with better breastfeeding outcomes. (161) Their work focused primarily on rural settings, and may not be generalizable to other areas. However, the work of McDonald et al. supports their finding; they report that increasing gestational age has a dose response on breastfeeding rates. For each additional week of gestation from 37 to 39 weeks, infants have better breastfeeding outcomes. (157)

Psychosocial Factors: Entwistle et al. found that breastfeeding outcomes were associated with the mother's self-confidence, and were influenced by the social context around breastfeeding in her home-life, as well as her knowledge about breastfeeding.

(176) While less readily generalizable, this qualitative analysis of in-depth interviews may have allowed the interaction between these psychosocial factors to become apparent to the researchers. These findings are in alignment with those from large national cohorts like that used by Singh et al. who found that breastfeeding duration increased with greater familial support. (160) Similarly, Kehler et al. used a longitudinal study design and found that women who were anxious during pregnancy were at higher risk for breastfeeding discontinuation. (162) Thus, several types of studies support an association between a mother's psychosocial context and her breastfeeding outcomes.

Feelings directly about breastfeeding have also been found to be associated with breastfeeding outcomes. A lack of confidence by the mother in her ability to breastfeed at 1- or 2-days postpartum was shown by Taveras et al. to be associated with breastfeeding discontinuation by 2-weeks in a prospective cohort study. (163) Work by Dunn et al. in Canada analyzed a telephone survey carried out at 6-weeks postpartum, and found that maternal confidence was associated with breastfeeding. (177) They found a stronger relationship for older mothers than for young, suggesting that age might moderate this association. A study of obesity and breastfeeding by Hilson et al. found that indifference toward breastfeeding was associated with shorter duration. (171) The same study identified an association between a mother's self-image and breastfeeding outcomes; the mother's dissatisfaction with her appearance was associated with shorter duration of breastfeeding. Similarly, ethnographic data suggest many women never consider breastfeeding or discontinue because of discomfort, embarrassment or lack of assistance. (161) Partner support has been reported to be important for breastfeeding outcomes as well. A randomized controlled trial (RCT) of a breastfeeding class for

fathers found a slight difference in breastfeeding rates at one month, 38% versus 35%, and a large difference at three months, 35% versus 19%. (178) Their study was small, but the study design adds credence to their finding.

Pregnancy wantedness is a factor discussed in the family planning literature, but which has not been explored in the breastfeeding literature for over 20 years. The wantedness of the pregnancy has been shown to be associated with other child outcomes such as antenatal care, stunting and later mental health for the child, signs that care giving may be different for infants born of unwanted or mistimed pregnancies. (179-181) Taylor et al. found that unintended pregnancies were negatively associated with breastfeeding initiation and duration for white mothers in a US-based study from 1995. (182) While pregnancy wantedness is a different construct from pregnancy intention, these results suggest that pregnancy wantedness may be a worthwhile and overlooked factor to consider for breastfeeding outcomes.

Program Participation: WIC participation has widely been reported to be negatively associated with breastfeeding outcomes. For example, Flower et al. found that receipt of WIC is associated with breastfeeding discontinuation by 6-months. (161) In fact, they reported that participation in WIC, independent of household income, is associated with worse breastfeeding outcomes suggesting that WIC participation is not simply a proxy for economic standing. However, this finding does not rule out the possibility that WIC participation is a proxy for SES, which has also been reported to be negatively associated with breastfeeding. (160) It is also possible that the association is directly related to the WIC program itself.

While the impact of groups like La Leche League have long been shown to be associated with breastfeeding outcomes, other peer counseling programs have gotten mixed reviews. (183-189) Pippins et al. found that receiving instruction about breastfeeding was positively associated with breastfeeding outcomes. (156) In contrast, Anderson et al. found no difference in breastfeeding continuation between treatment and controls in an RCT of breastfeeding education versus education plus peer counseling. (190) Another RCT of prenatal and postpartum breastfeeding support found that significant differences in breastfeeding rates persisted until 20 weeks. (191,192) One reason for the varying results may be that the effect of program participation must always be evaluated in the context of a particular program. The fact that a variety of studies report a beneficial association for breastfeeding programs suggests that designing such a program is possible.

Maternal Depression: Some studies have found no association between maternal depression and breastfeeding outcomes and others have found a connection. (156,159,177,193-196) A study by Dennis et al. found no association between depressive symptoms at one week postpartum and breastfeeding at the same time point, but did find an association with 4- and 8-week discontinuation of breastfeeding. (197) Bogen et al. did not find a direct association between maternal depression and breastfeeding outcomes but did none-the-less find an association with use of selective serotonin reuptake inhibitors (SSRI). Among those with lower depression scores (HDRS<9), SSRI use at 2-weeks was associated with not breastfeeding at 12-weeks. However, SSRI use by those with higher depression scores (HDRS >=9) was associated with continuation of

breastfeeding at 12-weeks. (159) So, this is an area of research that is still very active and not fully resolved.

Maternity Services and the Ten Steps to Successful Breastfeeding: In 1989, the UNICEF and the World Health Organization put forward the Ten Steps to Successful Breastfeeding, a set of recommendations designed to guide clinical care towards practices that would preserve and support a woman's ability to breastfeed. (198) The PROBIT study, conducted in 1996 to 1997 in Belarus, took advantage of the Belarusian healthcare system that allowed systematic assignment to intervention and control to show that the Ten Steps could have a substantial impact on breastfeeding outcomes. (199) The very strong design of this study has stood as a model for breastfeeding research. A very different type of study, one using in-depth interviews of a small group of women in the United Kingdom (UK) also found that maternity services affected breastfeeding outcomes. (176) Work by Declercq et al. and DiGirolamo showed that implementing even some of the steps results in improved breastfeeding outcomes. (200,201) More recent work, conducted in North Carolina, has shown that these practices have a significant effect on breastfeeding outcomes including initiation, continuation, and exclusivity. (202) Together these studies, using a variety of methods and settings, substantiate an association between the WHO Ten Steps and breastfeeding outcomes.

Other healthcare related factors are also associated with breastfeeding outcomes. According to McDonald et al. working in Canada, women who have undergone fertility treatments are less likely to breastfeed exclusively, as are those who do not attend prenatal care classes. (157) In the UK, where midwifery care is common, women who are

attended at birth by a midwife or family practice doctor are more likely to breastfeed exclusively than those attended by an obstetrician. (157) Late preterm birth, 37 to 39 weeks gestation, was found to have a dose response association with breastfeeding rates, with each week being better for breastfeeding. (157) Finally, Cesarean birth, whether planned or unplanned, was a risk factor for not breastfeeding compared to spontaneous vaginal birth. (157) The importance of the relationship with one's pediatrician has also been examined. In a prospective cohort study of psychosocial risk factors, Taveras et al. found that receiving encouragement to breastfeed from the woman's clinician was associated with breastfeeding continuation at 12-weeks. (163) Together these results from two large population-based samples suggest that healthcare-related factors may be associated with breastfeeding outcomes.

Breastfeeding Factors: A mother's plans about breastfeeding have widely been reported to be associated with breastfeeding outcomes. For example, in a prospective study following mothers from pregnancy through 12-weeks postpartum, Bogen et al. found that a mother's intention to breastfeed is associated with breastfeeding rates at two-weeks postpartum, and furthermore, intending to exclusively breastfeed is associated with 'primarily breastfeeding' as opposed to 'not breastfeeding' or 'partially breastfeeding.'(159) Likewise, using a PRAMS sample of over 16,000 mothers Colaizy et al. found that women with a "definite intention to breast-feed" were more likely to breastfeed for 4 weeks or more compared to those with "tentative intention."(203) Similar results come for the study of obesity and breastfeeding where a shorter intended duration of breastfeeding by obese mothers mediated some of the negative association

found between the breastfeeding and obesity. (171) Breastfeeding intensity and exclusivity has also been shown to be associated with later breastfeeding outcomes. For instance, exclusive breastfeeding at 2-weeks was found to be associated with continuing to breastfeed at 12 weeks. (159) Bogen et al. also found that prior breastfeeding experience was associated with breastfeeding outcomes. (159) Work by Taylor et al. explains this association further using a national probability sample of 2,115 women; they found that in families with more than one child, over 70% of women made the same feeding choice with each of their children. (204) Early breastfeeding experience may also be associated with later outcomes. Taveras et al. found that early breastfeeding problems were associated with breastfeeding discontinuation by 2-weeks. (163) Furthermore, Chapman et al. found that low breast-feeding frequency on day 1 postpartum was found to be negatively associated with breastfeeding duration. (169)

The strongest evidence of an association with breastfeeding outcomes exists for maternal age, parity, education, maternal employment, smoking, multiple gestation, and the mother's pre-birth intention to breastfeed. Racial differences have also been consistently reported, however, this is an area where improvements and change have also been seen. Factors with good evidence, but where some variation in the particulars for the association have been reported include income, SES, region, urbanicity, social support, partner support, participation in a peer support group, cesarean birth, and receipt of hospital practices included in the Ten Steps to Successful Breastfeeding. Evidence of an association with nativity, gestational age, mental health, attitude towards breastfeeding, depression, maternal confidence, fertility treatments, early BF experience, marital status, partnership status, obesity, pre-pregnant BMI, gestational weight gain,

pregnancy complications, pregnancy wantedness, instruction about breastfeeding have all been reported as well and are active areas of research and discussion in the field.

Behavioral Theory

The Theory of Planned Behavior, which is based on the Theory of Reasoned Action, posits that the most important determinate of behavior is behavioral intention. (205) Three factors predict an individual's behavioral intention: one's attitude toward the behavior, one's subjective norm, and one's perceived behavioral control. Each of these three factors, in turn, is determined by a weighted composite of many factors. That is, the influence of these underlying factors on behavioral intention is mediated by the attitude, subjective norm, and perceived control.

For breastfeeding, the Theory of Planned Behavior would suggest that the mother's intention to breastfeed would be the major determinant of whether or not she begins breastfeeding after birth. The mother's intention to breastfeed is one of the variables in this project, which will allow us to examine this hypothesis in two ways. First, bivariate analysis of breastfeeding intention and breastfeeding initiation will be used to examine the correlation between the intention and initiating the behavior as described in the Theory. Second, multivariate analysis will be used to assess whether there is an association between intention to breastfeed and breastfeeding duration, that is, continuing the behavior.

Some factors that could influence a woman's breastfeeding intention can also be assessed in this project. A series of questions on the maternity care related practices that a

woman experiences would contribute to both her perception of the subjective norm

around breastfeeding, at least within the hospital environment, and could also affect her

perceived behavioral control. For example, the question about whether the mother felt

supported by all facility staff in her infant feeding choice is, in essence, about her

perception of the subjective norm among the facility staff. So to, whether she is given a

formula sample bag at discharge could affect her sense of whether formula feeding or

breastfeeding is the normative behavior in her community. Her perceived behavioral

control could be influenced by several of the other hospital practices that were part of the

questionnaire. Being given immediate skin-to-skin contact with her infant after birth

gives the mother the ability to breastfeed if she wishes. Likewise, rooming in, i.e., having

her baby with her at least 22 out of 24 hours, gives her access to her child for feedings.

Finally, being visited by a lactation consultant (LC) and having a feeding observed by an

LC could improve her sense of behavioral control by getting help and/or reassurance, and

also through feeling that there are resources available to assist her should she need them.

By exploring these factors in both the analysis of breastfeeding initiation and

breastfeeding duration, these parts of the Theory of Planned Behavior can be tested in

this project.

Conceptual Model

Figure 2: Conceptual Model
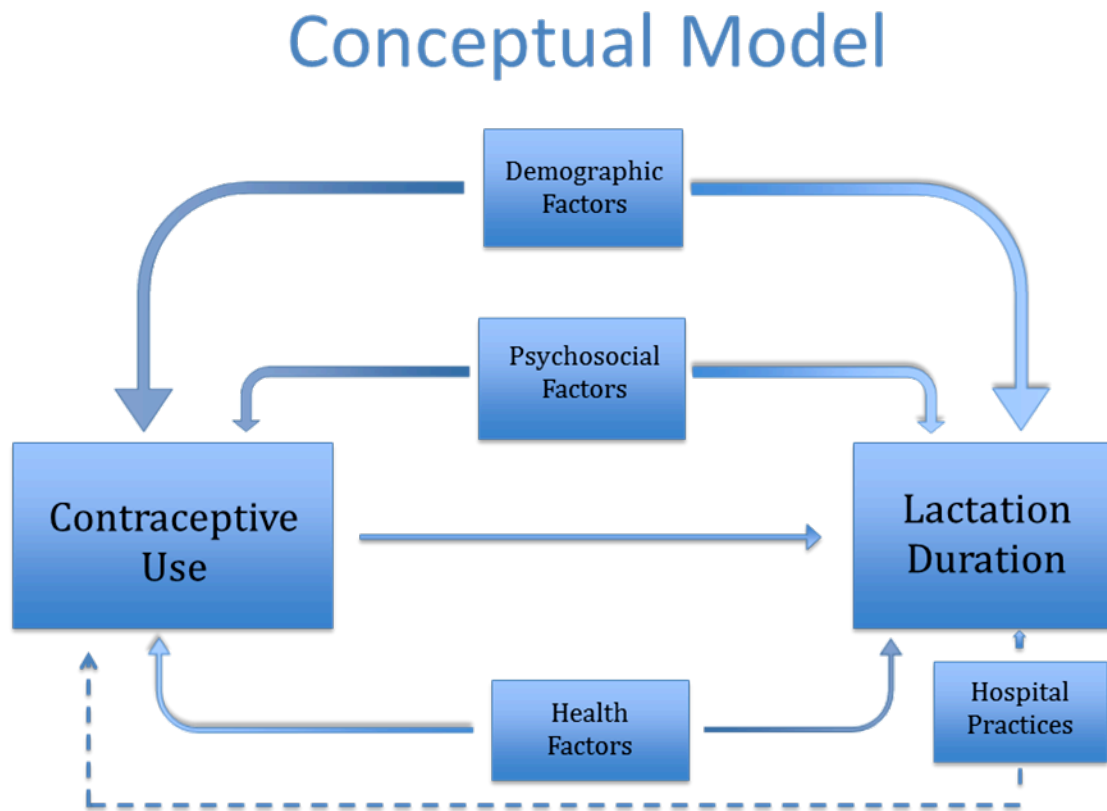
The aim of this project is to explore the possible causal pathway from contraceptive use to lactation duration diagramed in the conceptual model above. As the model shows, a variety of factors likely influence contraceptive use and breastfeeding duration. Not only will those factors need to be addressed in the statistical analyses to control for their potential confounding effects, but they also represent potential intervention points and constraints when discussing the practical implications of this project's results.

The factors that influence contraceptive use and/or lactation duration are broken down into four main types: demographic, social, health, and maternity-related. Demographic factors include traits of the woman or her household which are either not changeable, or would not generally be changed in response to breastfeeding and family planning. This includes the mother's race and ethnicity, her age, her socio-economic status, her level of education, the region in which she lives, her enrollment in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), and her marital status.

Social factors are associated with the mother's plans and ideas that influence her approach to contraception and lactation. Importantly, these factors have the potential to be changed, though it may be difficult or unlikely that they will be. Many things may fall into this category, and each woman may have unique priorities that she takes into account when making choices about contraception and breastfeeding. However, some common issues are her pre-birth intention to breastfeed, her plans about working after the birth, the perceived support from people whose opinions she values, and her feelings about whether she wanted the pregnancy.

Breastfeeding is, at its core, a biological and behavioral process. (48-50) As such, health factors for both mother and baby could affect this process. The main factor available in the dataset is whether the infant spent time in the Neonatal Intensive Care Unit (NICU). NICU policies and practices may directly influence a dyad's ability to initiate and continue breastfeeding. It is also a proxy for infant health status, particularly prematurity, which is known to be related to developmental challenges to breastfeeding like lack of coordination of the suck-breathe-swallow rhythm necessary for successful

51

nursing. Therefore, NICU stay is an important measure that covers many of the health-related issues that impact breastfeeding from the infant's side of the equation. Knowledge about the interaction of health-related issues and breastfeeding outcomes could inform the implementation and targeting of programs, and could lend further importance to prevention efforts for the health issues themselves.

Finally, factors related to the healthcare system are known to play an important part in successful breastfeeding initiation and establishment, and offer one of the most fruitful intervention points in improving breastfeeding outcomes. The Ten Steps to Successful Breastfeeding developed by the WHO gives a framework for best practices related to maternity care and breastfeeding. They delineate concrete actions the facility and staff should take to ensure that every mother has the opportunity, access, information, and support to breastfeed if she chooses.

APPROACH

Study Overview

This document and the articles prepared for publication will explore the relationship between predisposing factors and breastfeeding outcomes, and then will utilize these relationships in the study of the impact of contraception on breastfeeding duration. An aim of this work is to inform clinical practice from labor through the early months postpartum, as well as give useful information for programs that support and increase breastfeeding in the United States. The primary focus of this project is elucidating the impact of hormonal contraceptive use while breastfeeding on the duration

of breastfeeding. To fully understand these relationships, the associations with socio-demographic and health variables will also be explored, as well as the relationship, if any, between these factors, hospital practices and postpartum contraceptive use.

Study Sample

This project utilizes secondary data from a data set that had, as its primary purpose, assessing the impact of *The Period of Purple Crying* education campaign in North Carolina. This CDC-funded study included an intervention phase with education for parents about normal crying behavior of infants as a means of reducing child maltreatment, in particular, shaken baby syndrome, and a follow-up survey to which a small set of additional questions was added. The additional questions related to breastfeeding, other infant feeding practices, and healthcare practices during delivery and immediately postpartum, and contraceptive use. These variables were added with the aim of identifying modifiable practices, barriers, and influences that impact breastfeeding success in order to inform interventions to improve breastfeeding outcomes in North Carolina and nationally. Factors associated with disparities in breastfeeding initiation and/or continuation were of particular interest since these not only offer a high-impact opportunity to improve community breastfeeding rates, but also an important touch-point to improve health disparities for target populations with disproportionately poor breastfeeding, mortality and morbidity rates.

The survey was conducted in 2010-11 by telephone interview of new mothers drawn from birth certificate records in North Carolina. About 2000 women were selected from the approximately 130,000 annual live births in the state. Mothers of two- to three-

month-old infants were targeted, though the actual sample included mothers with both older and younger infants (range 0 to 36 months). The birth certificates were selected with over-sampling for Hispanic maternal ethnicity (some Hispanic origin, no Hispanic origin), baby's birth date (<2 months, 2-3 months), hospital size (small, medium, large based on live births per hospital), and location (urban/rural based on the NC Rural Profile 2004). A random sample was taken from the birth certificate data using a sampling rate of 2 for Hispanic origin and 1.5 for baby's birth date <2 months. Proportionate sampling rates for urban/rural location and hospital size were used. Once selected, the mothers' telephone number was back-matched from name and address information on the birth records, and only those for whom a telephone number could be matched and which reached a household in North Carolina were considered eligible. The interview was conducted in English or Spanish only, all other languages were ineligible. If more than one child met the criteria, the one referenced on the birth certificate was the referent for the survey. The female parent or female legal guardian was interviewed.

Data collection was carried out by the Carolina Survey Research Laboratory at the University of North Carolina at Chapel Hill. The survey was conducted in a single interview, and therefore, the data are cross-sectional in nature. The survey was conducted from April 21, 2010 to March 17, 2011. A Spanish language version of the questionnaire was translated from the English and verified by DTS Language Services, Inc. of Raleigh, North Carolina. At least 12 call attempts were made including at least one weekend, one evening and one daytime call before a potential participant was dropped.

Among the eligible participants chosen at random from North Carolina birth certificate records, there were 1,644 (98.5%) complete interviews and 25 partial

interviews. The partial interviews were included in the data set, but had a high percentage of missing values. An additional 642 women were eligible to participate in the survey, but chose not to, and the eligibility of another 1896 women could not be determined due to a failure to successfully make contact with these households. Thus, the survey response rate was estimated to be between 52% and 72% depending on what proportion of the group with unknown eligibility status one assumes would have been eligible.

This dataset is particularly useful in addressing the question of postpartum contraceptive use and breastfeeding because of the level of detail in the questions added on these two topics. It is relatively rare for a survey to ask about postpartum contraceptive use and breastfeeding and to do so with well-designed questions for both topics.

These data are particularly valuable for the health-system related measures, capturing many of the modifiable factors in delivery and breastfeeding support. How these factors relate, if at all, to contraceptive use is one of the novel dimensions of this work. While some aspects such as mode of delivery are not available, other factors like the timing of the first feeding, which is often not queried, are available. Moreover, a series of questions relating to the Ten Steps to breastfeeding success, a WHO program to encourage good hospital practice in support of breastfeeding, enables a rich exploration of this initiative, improving the ability to both control for confounding and draw inferences for policies and programs. Lastly, this data set is unusual in that it includes questions about pregnancy wantedness, something few surveys consider. Therefore these data provide an important opportunity to further the knowledge available on the relationship among these variables.

Analytic Sample

This dataset included 1,669 women of whom 1,443 intended to breastfeed (86%), 206 did not intend to breastfeed, and 20 did not respond about their breastfeeding intentions. Birth control use was reported for 1,655 women, of whom 1,321 reported using some form of birth control since delivery (79%), while 334 had not used birth control since giving birth, and 14 did not respond. Hormonal contraception was used by 47.5% of women, or 792 respondents. (Table 1)

The entire sample was used for this project. Since the sample was drawn from state birth certificate data, it represents a random cross-section of live births in North Carolina during this recruitment time-period. No further restrictions were applied, notably no restriction on health status of either the mother or baby. Such challenges, in and of themselves, could have limited a mother-baby dyad's ability to breastfeed. No sample weights were used to adjust the data to be specifically representative of either the North Carolina or US population or any other demographically specific group. In this way, the sample is reflective of the general NC population who have telephones and are reachable by phone, and inference to programs and practices aimed at the entire population of newborns and their mothers must be carried out with caution.

Table 1: Description of the Sample (N=1,669) from a survey evaluating the Period of Purple Crying Intervention Program, 2010-11.

	n	%			n	%
Maternal Age			**Income**			
<20	104	6.2%		<20K	283	17.0%
20-24	217	13.0%		20 to <40K	300	18.0%
25-29	375	22.5%		40 to <60K	182	10.9%
30-34	541	32.4%		60 to <80K	220	13.2%
35-39	314	18.8%		80 to <100K	181	10.8%
>=40	92	5.5%		>=100K	325	19.5%
Missing	26	1.6%		Missing	178	10.7%
Race/Ethnicity			**NICU Stay**			
Non-Hispanic White	1,069	64.1%		No	1,442	86.4%
Hispanic	316	18.9%		Yes	198	11.9%
Non-Hispanic Black	207	12.4%		missing	29	1.7%
Asian	33	2.0%				
Native American, Alaskan Native	11	0.7%	**Older Sibling**			
Native Hawaiian, Pacific Islander	3	0.2%		Yes	1,059	35.1%
Missing	30	1.8%		No	586	63.5%
				Missing	24	1.4%
Maternal Education						
			Intended to Breastfeed			
< High school	207	12.4%		No	206	12.3%
High school/GED	486	29.1%		Yes	1,443	86.5%
College/Graduate	649	38.9%		Missing	20	1.2%
Graduate Degree	300	18.0%				
Missing	27	1.6%				
			Ever Breastfed			
Pregnancy Intention				No	250	15.0%
Wanted	975	58.4%		Yes	1,398	83.8%
Wanted, not at this time	413	24.7%		Missing	21	1.3%
All pregnancies are wanted	228	13.7%				
			Time of Breastfeeding Initiation (N=1398)			
Not Wanted	21	1.3%				
Missing	32	1.9%		Never	250	15.0%
				<1 hour	607	36.4%
Contraceptive Use				1-2 hours	279	16.7%
None	294	17.6%		2-6 hours	256	15.3%
Non-hormonal	356	21.3%		6-24 hours	92	5.5%
Progesterone-only	383	22.9%		>24 hours	144	8.6%
Combined estrogen/prog.	166	9.9%		missing	41	2.5%

57

MEASURES

Key Variables

Breastfeeding Duration: The primary outcome variable of interest is breastfeeding duration, which was calculated based on the mother's response to several questions. Near the beginning of the survey, women were asked how old their baby was in months. The baby's age in weeks was then calculated by multiplying this response by 4. Later in the survey, women were asked, "Are you still breastfeeding?" Those who answered "no," "refused," or "don't know" were then asked, "How long did you breastfeed?" Their answer was recorded in weeks and used as their final breastfeeding duration. This response was also checked against the baby's age calculated from the mother's earlier response, and any responses that exceeded the baby's age by more than three weeks were dropped from the analysis as being implausible; no subjects were dropped due to implausible values for infant age.

For those who responded "yes" to the question "are you still breastfeeding?," breastfeeding duration was calculated based on the baby's age reported in months at the beginning of the survey. To convert it to weeks, their response to this question was multiplied by 4. On average, women would have nursed for the number of months they reported, plus about half of the following month. Therefore, an additional two weeks was added to the month–to-weeks conversion calculated above to account for the average number of weeks represented by whole months, which was the way this question was asked. Since the ultimate breastfeeding duration is unknown for these respondents, their data are right censored.

Contraceptive Use: Contraceptive use was examined as both an outcome and an exposure in this project using the respondent's answer to the question, "Which of the following birth control method or methods have you used since [BABY NAME] was born?"

Respondents were allowed to identify up to eight different methods used, but no one reported more than three. They were also able to specify "other" and if so were asked to describe the method they used. From these responses, additional categories were coded by hand: Tubal Ligation/Hysterectomy/Surgery, Vasectomy, Nuva Ring, Spermicide, Pill-Unknown type, Implanon, Patch. All verbal responses were readily identifiable as falling into one of the resulting 15 categories. Where more than one contraceptive type was reported, the woman's contraceptive use was classified by a single type in the following order: combined estrogen/progestin, progestin-only, non-hormonal methods, no contraceptive used.

Where more than one method was used, the order and trimming of their use is unknown, and for all women information on the dose of hormonal contraceptive was not available. Information on the timing of contraceptive use was not obtained in the survey, and therefore the timing of use relative to breastfeeding cessation cannot be determined. This leaves open the possibility that breastfeeding cessation preceded the contraceptive use in which case any association found would run in the opposite direction to the study question, i.e. breastfeeding cessation leading to contraceptive use. The age of the infants in this population and the fact that a large number of the participants were still nursing at the time of the study mitigate, but do not eliminate this possibility.

Independent Variables

Maternal Age: Maternal Age was determined from the respondent's answer to question F01, "How old are you?" Ages in the sample were measured in years and ranged from 14 to 46. All responses were considered plausible and therefore none were eliminated for being out of range. The modeling of maternal age was explored both as a continuous variable and as a categorical variable to determine which better captured the relationship between maternal age and the outcomes of interest, breastfeeding duration and contraceptive use.

Maternal Race/Ethnicity: Infant race/ethnicity was used to capture the effects of race and ethnicity on the outcomes of interest. For breastfeeding, race/ethnicity is likely to represent social and cultural mechanisms of influence and not likely to represent biological differences in a woman's ability to breastfeed.

　　The mother's race/ethnicity was determined from a combination of the question "Are you Hispanic or Latino?," and the question "Which one or more of the following would you say is your race?" Based on these two questions, categories for Non-Hispanic White, Non-Hispanic Black, Hispanic, and Other were constructed. The category "other" included those who identified themselves as Asian, Native American/Alaskan Native, Native Hawaiian/Pacific Islander, and other.

　　Given that respondents could identify themselves as multi-racial, a rubric for how to assign a single race/ethnicity to each participant was necessary, and is presented in Figure 3. Women who identified themselves as Hispanic were considered Hispanic

regardless of their race. Of those remaining, women who identified themselves in a single racial category were classified as that race. Women who identified more than one race were asked whether they considered themselves White or non-white. Those who responded "white" were coded as white. Among those who responded "non-white" a hierarchy was used with the overall goal of being as conservative as possible based on knowledge of US breastfeeding rates for minority populations, tending to bias the results towards the null (no difference in breastfeeding pattern by race) rather than away from it.

Figure 3: Decision Making Rubric for Maternal Race/Ethnicity
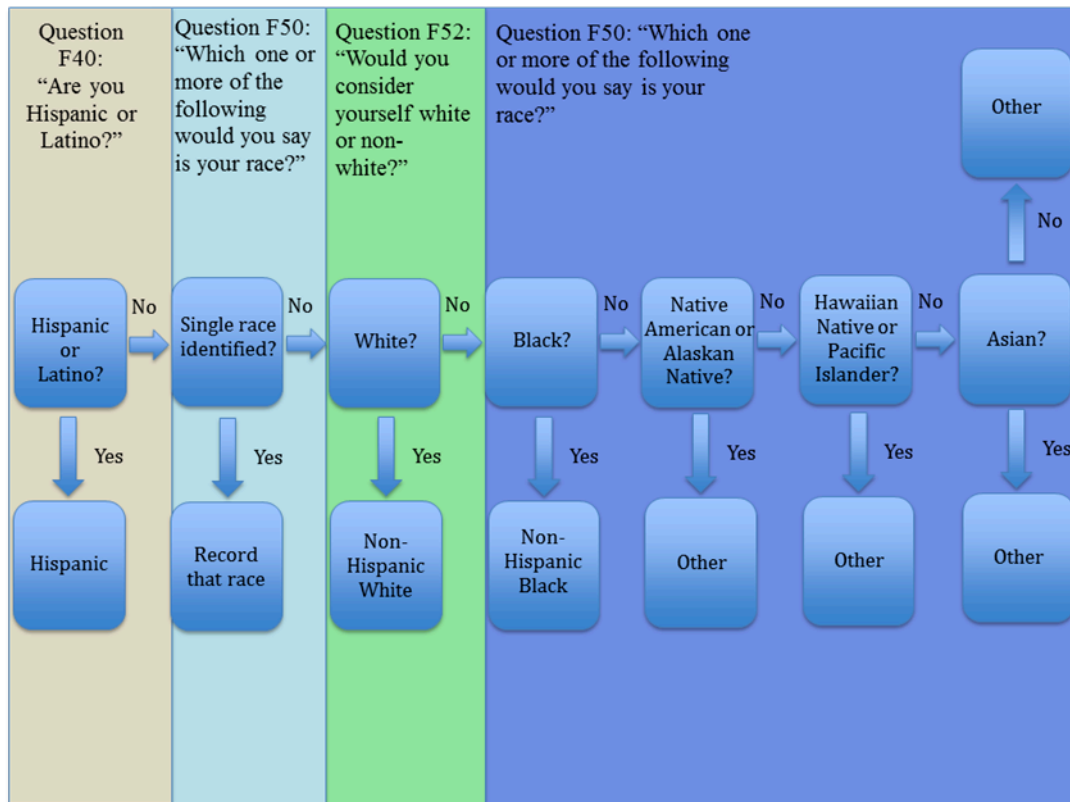
Maternal Educational Attainment: Maternal education was modeled as a categorical variable drawn from the single question about education level asked on the survey, which was "What is the highest level of school you've completed so far?" The available options

were "below high school," "high school graduate or GED," "College degree (associates or bachelors)," and "graduate degree."

Household Income: Household income was based on a series of questions that together identified the respondent's income level within a $20,000 range. The initial question was "Is your total family income, before taxes, under or over $40,000?" Respondents could select "under $40,000," "over $40,000," "exactly $40,000," "refused," or "don't know." Follow-on questions sequentially narrowed the response to finer and finer ranges. For example, those who identified their family income as over $40,000 were then asked "Is your total family income over $60,000?," and could respond "no," "yes," "refused, "or don't know."

Parity Proxy: First Live Birth: Respondents were asked whether they had any older biological children. While this does not directly ask about parity, a factor associated with breastfeeding duration, it is a reasonable proxy since infant and child mortality in the US is low. More detailed information about prior breastfeeding experience, the number of older children, and non-living biological children is not available. While these are likely also associated with maternal choices, a variable like this one that essentially captures whether the child in the survey is the oldest living child is a reasonable approximation of the influence of these factors. A dichotomous (yes/no) variable was based on the participant's response to the question, "Do you have any biological children older than [BABY NAME]." Answers of, "refused," and, "don't know," were coded as missing.

NICU Stay: Admittance to a Neonatal Intensive Care Unit (NICU) has been shown to be associated with breastfeeding initiation and duration, although evidence about direction is mixed. A dichotomous variable (yes/no) for NICU stay was coded based on the participant's response to the question, "Did [BABY NAME] spend any time in the neonatal intensive care unit or "NICU" before being discharged from the hospital?" Responses of "refused" or "don't know" were coded as missing.

Breastfeeding Intention: The mother's intention to breastfeed prior to giving birth was queried with the question, "Before [BABY NAME] was born, did you <u>intend</u> to breastfeed?" A dichotomous variable (yes/no) was coded from the responses with, "refused," and "don't know," coded as missing.

Length intended to breastfeed: Women who identified themselves as having intended to breastfeed before birth were then asked how long they intended to breastfeed, and their answer was recorded in weeks. If they answered in months, the survey administrator was instructed to multiply their response by 4 and to record this.

Ever Breastfed: Women were asked, "Did you ever breastfeed [BABY NAME]?" Their response was recoded as a dichotomous variable (yes/no) with "refused" and "don't know" coded as missing.

Pregnancy Wantedness: The degree to which the pregnancy was desired was queried using a scale for pregnancy 'wantedness' put forth by the WHO. Mothers were asked,

"Would you say your <u>pregnancy</u> with [BABY NAME]…," and then given the following 4 options: "…was wanted <u>and</u> occurred at about the time you planned," …was wanted, but not at this time, "…was wanted because all pregnancies are wanted, or, " "…was not wanted." Respondents could also answer "refused" or "don't know" both of which were coded as missing values. Only 8 respondents identified their pregnancy as not wanted, therefore this category was grouped with the mistimed pregnancies. To evaluate the best coding to captured the relationship between pregnancy wantedness and the outcome of interest, either contraceptive use or breastfeeding duration, coding pregnancy wantedness as either a categorical variable (one to three) or as dummy variables for each category was explored. Dummy variables were used for all analyses.

Hospital Practices: Women were asked questions related to the Ten Steps to Successful Breastfeeding identified by the WHO as important healthcare related practices to ensure that breastfeeding is supported by the healthcare system. Women's responses to each item were captured as a dichotomous variable (yes/no). All women named at least one practice, therefore, if a respondent did not identify a practice it was recorded as a "no" for that practice. The following practices were evaluated: immediate skin-to-skin contact between mother and baby, visit by a lactation consultant or breastfeeding specialist, breastfeeding observed by a lactation consultant or breastfeeding specialist, mother felt supported by all hospital staff in decision regarding breastfeeding, baby was with the mother at least 22 out of every 24 hours, mother received a formula sample bag. These practices were examined both individually and as a composite, ordinal variable for the

number of practices experienced by the mother, to see which method was best in the model.

The timing of breastfeeding initiation has important biological implications and is often a function of hospital practices. Among respondents who said that they had ever breastfed, women were asked how many hours it was until the first breastfeeding. Their responses were captured in four time bins, which were coded as a categorical variable: less than 1 hour, one to two hours, two to 24 hours, and over 24 hours.

Missing Data

A complete case analysis was done, excluding respondents with missing values for any variables used in that specific analysis. With the exception of the variables for household income (10.7% missing) and intended duration of breastfeeding (17.8% missing), the level of missing data in this sample was very low, between 1% and 3% for all variables. Two analyses, a likelihood ratio test and forest plots of the parameter estimates for the covariates, were used to determine that income could be excluded from the analysis without significantly affecting the models. The high degree of missing data for intended breastfeeding duration was thought to be non-random, potentially representing differences in confidence, determination, and/or education about breastfeeding, which could be reflected by having an intended duration or not having a clearly defined plan for this. Therefore, both income and intended breastfeeding duration were excluded from the model.

HYPOTHESES

Aim 1: To evaluate the association, if any, between demographic, social, and healthcare factors and the likelihood of weaning.

Hypothesis: Demographics, social factors, and healthcare practices experienced during labor and immediately postpartum are associated with the duration of breastfeeding.

Aim 2: To assess whether there is an association between demographic, social, and maternity-related healthcare factors and contraceptive use in the postpartum time frame.

Hypothesis: There are associations between demographic and healthcare factors such as race/ethnicity, pregnancy wantedness, income, maternal age, education, and hospital practices, and the use of contraceptives, including the specific type of contraceptive used, in the postpartum time-period.

Aim 3: To assess the impact of the postpartum use of progestin-only contraceptive methods on duration of any breastfeeding.

Hypothesis: Women who use progestin-only contraception postnatally are more likely to cease breastfeeding than women who do not use contraception and women who use non-hormonal methods of contraception.

Aim 4: To assess the impact of the use of combined progestin/estrogen contraceptive methods in the postpartum period on breastfeeding success, measured as the hazard of breastfeeding cessation.

Hypothesis: Women who use combined progestin/estrogen contraception in the postpartum period are less likely to be breastfeeding at each time-point than women who do not use contraception, women who use non-hormonal methods, and women who use progestin-only contraception.

STATISTICAL ANALYSIS

Analytic Sample

For analysis of breastfeeding duration in the entire population, the sample size was 1,573, 94.2% of the original sample. For analysis of breastfeeding duration limited to those who initiated breastfeeding, the sample size was 1,333 of the 1,429 eligible women (93.3%). For the analysis that included contraceptive information and was limited to women who initiated breastfeeding, the sample size was 1,319 of the 1,429 eligible study participants (92.3%).

Descriptive Statistics

Descriptive statistics for all variables are presented for the sample as a whole and for strata based on the type of birth control used after birth and by breastfeeding initiation. This informed a discussion of demographic variation in these factors. Counts and percentages of the population/strata are presented for dichotomous and categorical. Mean, standard deviation, minima, and maxima are shown for continuous variables

Analyses for Aim 1

A Cox proportional hazards model as described by Allison was used to perform a survival analysis of breastfeeding duration. (206) The analysis was carried out in two ways: among the entire study sample and among only those who initiated breastfeeding. These analyses provided a meaningful measure of the hazard of breastfeeding cessation from which survival curves stratified by study covariates were drawn. Time to breastfeeding cessation was the dependent variable and maternal, infant, and healthcare factors were the independent variables. Because some study participants are still nursing at the time of their interview, some of the data are right censored. The censoring should be random due to the random sampling study design. Moreover, censoring should be less of an issue at earlier time points where the sample includes many participants that have breastfed beyond this time point. The discrete method was used to account for the fact that there was a high degree of tied data that likely reflects that events actually occur at the same time-point for the women who did not initiate breastfeeding.

To select appropriate control variables, an initial set of variables was identified based on the theoretical relationships between factors described in the literature. An initial analysis was run using all variables identified and available in the dataset. Those with a p-value less than 0.05 were considered significant and were retained in the model. Additionally, variables that were expected to be significantly related to the outcome, but were not significantly associated with the outcome in the original model were explored using Likelihood ratio tests, Bayesian Information Criterion (BIC), Akaike Information Criterion (AIC) tests to assess model fit with and without these variables. Variables for region and income were dropped from the model because they were neither significant,

nor improved the model fit. The BIC and AIC were also used to determine the best

modeling for maternal age. Variables for intention to breastfeed and intended duration of

breastfeeding were co-linear. Intention to breastfeed was retained in the model and

intended duration was dropped because the high degree of missing data (17.8%) for

intended duration was believed to be non-random (discussed elsewhere). Other variables

were not co-linear, although in an analysis of the ability to impute the missing values for

income, intention to breastfeed was strongly predictive of income. Income was also

dropped from the analysis as described above.

Analyses for Aim 2

A log binomial regression was performed with type of contraceptive used as the

dependent variable and demographic, social, and healthcare factors as the independent

variables according to the following model:

Logt $P(Y=1) = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_4 X_4 + \beta_5 X_5 + \beta_6 X_6 + \beta_7 X_7 + \beta_8 X_8 + \beta_9 X_9 + \beta_{10} X_{10} + \beta_{11} X_{11} + \beta_{12} X_{12} + \beta_{13} X_{13} + \beta_{14} X_{14} + \beta_{15} X_{15} + \beta_{16} X_{16} + \beta_{17} X_{17} + \varepsilon$

Y: Whether a particular type of contraceptive is used
X_1: Breastfeeding intention (yes/no)
X_2: Breastfed ever (yes/no)
X_3: Intended duration of breastfeeding
X_4: Maternal age
X_5: Maternal race/ethnicity
X_6: Maternal educational attainment (yes/no)
X_7: Pregnancy wantedness
X_8: 1st live birth (yes/no)
X_9: NICU stay (yes/no)
X_{10}: Baby's sex
X_{11}: Timing of first breastfeed
X_{12}: Immediate skin-to-skin contact between mother and baby
X_{13}: Visit by a lactation consultant or breastfeeding specialist (yes/no)
X_{14}: Breastfeeding observed by a lactation consultant or breastfeeding specialist (yes/no)
X_{15}: Mother felt supported by all hospital staff in her breastfeeding decision (yes/no)

X_{16}: Baby was with the mother at least 22 out of every 24 hours (yes/no)
X_{17}: Mother received a formula sample bag (yes/no)

The analysis was limited to those who initiated breastfeeding. Results of the log binomial regression are informative for discussion of associations between the independent variables in the final model and the dependent variable, type of contraceptive used. The independent variables provide a list of considerations that can inform policies and programs for intervention. A causal relationship is not assessed by this analysis however.

Analyses for Aims 3 and 4: Propensity Score and Inverse Probability Weight

A Kaplan-Meier survival analysis was performed with breastfeeding duration as the dependent variable and type of contraceptive used as the primary independent variable. Kaplan-Meier curves are appropriate for this analysis because they allow the relationship between the dependent and independent variable to take any form, i.e., the model is non-parametric. Since clinical observation suggests that the resilience of the biological systems underlying breastfeeding might be more fragile in the early postpartum than later on, it is valuable to choose a statistical model like this one, which does not make assumptions about the nature of the relationship, and furthermore, allows the mathematical relationship to be different at different time-points in the breastfeeding life-cycle.

The independent variable of interest, type of contraceptive used, was not randomly assigned in this study. Cole and Hernán suggest that in studies without random assignment of the 'treatment', unadjusted Kaplan-Meier curves can lead to issues with confounding due to group-level differences between the treatment and control

70

populations. (207) They suggest using inverse probability weights based on propensity scores to address this issue, allowing the propensity score to represent the likelihood of being in the treatment or control based on the covariates that underlie the propensity score calculation. The goal is to balance differences that exist in the distribution of other variables between the treatment and control groups that make them imperfect counterfactuals, that is, to find a mathematical way of accounting for the systematic differences between the groups. In this case, adjustment for the factors found in Aim 2 to be significantly associated with type of contraceptive used is important to control for confounding by these factors as described by Robins et al. (208) The assumption of propensity scores is that there are no unmeasured confounders, if this assumption is met, then the difference between the outcomes of the treatment and control groups can be considered the average treatment effect. (209)

Thus, a propensity score was estimated for each study participant using the variables identified in Aims 1 and 2. This score was then used as the basis of an inverse probability weight (IPW) used in the analysis of Aims 3 and 4. The IPW captures the marginal probability of a study subject receiving the treatment that they actually received given the exposures, or covariates, observed for that individual. In other words, how much does that individual look like the rest of the group in which they are a member, either treatment or control. Because it is an inverse, group members who look like the opposite group are weighted more strongly than members who look like their own group, and this is done in proportion to their similarity to the other group.

Inverse Probability Weight:

$W_i = 1 / f(x)$

Where:

W_i = the inverse probability weight for individual i

= the inverse probability of individual i receiving the treatment they received (X) given, or conditional, on the observed covariate vector Z

$f(x)$=stabilized weights which are a function of $(X|Z)$ where

X = the independent variable or treatment

Z = covariates or confounders

An advantage of using propensity scores is that they allow you to estimate what the population effect would be if everyone received treatment. However, this interpretation relies on the assumption of no unmeasured confounders. That is, that all confounders have been measured and included in the creation of the propensity score.

Analyses for Aim 3

To explore a relationship between use of progestin-only contraceptive methods and duration of breastfeeding, a Kaplan–Meier survival analysis was performed using inverse probability weights as described above. The analysis compared the use of any progestin-only contraception method with use of a non-hormonal method and with no use of contraception. The composition of each group was as follows:

Progestin-only:
Mini-Pill
IUD with Hormone, aka Mirena
Contraceptive shot, aka Depo-Provera
Implanon

Non-hormonal:
IUD with Copper
Condom
Spermicide
Vasectomy
Tubal Ligation/Hysterectomy/Surgery

No Contraception:
No contraception used

Biologically, non-hormonal methods and no contraceptive use should not interact with the mechanism of breastfeeding, and therefore might reasonably be analyzed together. Socially, however, these groups might be quite different in ways that would confound the breastfeeding data. For example, people who do not use contraception after birth could differ from those who use contraception in terms of their plans to breastfeed since some women perceive familiar forms of contraception as being contra-indicated for breastfeeding. Moreover, the Lactational Amenorrhea Method (LAM), which was not explicitly mentioned on the survey, is an effective form of birth control for those who breastfeed according to its guidelines for the first six months. Taking this rationale into account, non-hormonal methods were analyzed separately from no contraception.

Analysis of Aim 3:
All Progestin-only methods vs. Barrier methods
All Progestin-only methods vs. No contraception

Analyses for Aim 4

A relationship between the use of combined estrogen/progestin methods of contraception and breastfeeding duration were examined using the Kaplan-Meier survival analysis described above utilizing propensity score based inverse probability weights to control for social, demographic, health, and healthcare factors. As with Aim 3, an analysis of all forms of combined hormonal contraception was done with comparison

groups of progestin-only methods, non-hormonal methods, and no contraception. The

categories were defined as in Aim 3 with the addition of the following grouping:

<u>Combined estrogen/progestin methods</u>
Combined pill
Nuva ring
Contraceptive patch

The following comparisons will be made:

<u>Analysis 1:</u>
Combined estrogen/progestin vs. Progestin-only
Combined estrogen/progestin vs. non-hormonal methods
Combined estrogen/progestin vs. no contraception

LIMITATIONS

Although the project improves on the designs of previous investigations, there are

several limitations to the data and analysis.

Competing Reasons for Breastfeeding Cessation: In the United States, there is a large

drop-off in breastfeeding rates during the first year, which could affect the ability of my

analyses to detect any associations between all the factors considered. Unmeasured

factors that contribute to breastfeeding cessation could be wrongly attributed in this study

as an effect of contraceptive use. The use of propensity scores is intended to address the

multi-faceted nature of this topic area and, therefore, address this concern. If factors such

as social, demographic, and healthcare are more important to breastfeeding cessation than

biological factors, it may be difficult to detect the biological impact of contraceptive use if there is residual confounding.

Sample Population: The sample population was selected from North Carolina Birth Certificates and contacted by telephone. To the extent that differences exist between those who are available by landline telephone and those who cannot be reached by this means, including those who do not have a landline telephone, my sample may be biased. For instance, people who use cell phones exclusively would not be available by landline telephone, and this could disproportionately include younger, poorer, and more transient mothers. Moreover, if willingness to participate were not randomly distributed, my sample would be biased. These concerns are addressed in two ways. First, the initial selection process from birth certificate records, which was random, provides the best possible foundation for sample selection. In addition to this, many measures were undertaken to contact potential subjects including attempting to make contact at different times of the day and week, multiple attempts to contact women, and contact attempts over several months. Furthermore, if the potential participant declined, efforts were made by specially trained personnel to convince the potential study subjects to participate. In sum, these efforts should minimize the potential issues.

Questionnaire: The study design relied on maternal self-report and is therefore subject to bias, in particular, recall bias and bias in reporting perceived positive behavior. Survey respondents reported their answers to a survey administrator, potentially introducing a bias in avoiding stigma. However, to mitigate these issues, specific efforts were made to

the wording of the questionnaire and survey administrator's demeanor and tone such that the questions would be perceived as neutral.

A small number of study participants (25, 1.5%) stopped responding mid-way through the questionnaire, leading to a large amount of missing data for these participants. This could introduce bias since those who complete the survey may differ in some way from those who are unable or unwilling to do so. To obtain a complete questionnaire response from each respondent, efforts were made by the data collection company to re-contact these participants if at all possible. Still, about 1% of participants were unable or unwilling to complete the questionnaire. These analyses will use a complete case analysis design, such that participants with missing values will be excluded in the analytic sample.

The breastfeeding and contraception portion of the survey were imbedded in a larger survey on infant crying behavior and parenting. Adjustments to the skip pattern on the breastfeeding questions makes analysis of exclusive breastfeeding possible only for those who are still nursing, and therefore analysis of this outcome is not proposed as part of this project. This is unfortunate, since exclusivity is a relevant outcome of interest in relation to milk supply, a potential point of impact for exogenous hormones like those in hormonal contraception. The cross-sectional study design led to a high degree of censored breastfeeding data. A longitudinal study design could have captured the timing of breastfeeding cessation and contraceptive use more thoroughly. In spite of this, the other benefits of this data set make it a valuable and appropriate choice for this project.

INNOVATION

This project is innovative in three ways. First, the data were collected from a US cohort, which addresses a gap in the literature regarding the specific interaction of US breastfeeding patterns and norms with the biological pressure, if any, of hormonal contraception. Because breastfeeding is a multi-faceted biological process with many opportunities to be affected by the mother's behavior, practices of the healthcare system, social and psychological context, and social norms including laws and regulation, this topic is, by necessity, culturally specific. Examining this topic in a contemporary US setting, then, is important for informing policy and interventions that are appropriate for our cultural context and current contraceptive formulations and products.

Second, this project improves significantly on the methodology used in much of the literature. The use of both survival analysis and propensity scores is a significant improvement on the techniques used in nearly all of the previous studies. Indeed, only one of the articles reviewed used survival analysis, and use of this technique was specifically identified by Kapp et al. as being superior for this topic area. (105) The vast majority of the background literature was impacted by an inability to adequately address confounding. Yet, for both breastfeeding and contraceptive use, a wide variety of factors are known to be associated with outcomes. Thus making it especially critical to isolate the biological interaction of interest from all the other influences. Propensity scores offer a methodological and theoretical advantage over other techniques used to control for confounding, provided they include the relevant factors. Furthermore, they may allow examination of causality whereas other methods enable discussion only of association. To

the best of my knowledge, propensity scores have never been used to examine breastfeeding and contraception. Therefore, this project innovates by introducing a new statistical method, propensity scores, to the field and by using survival analysis on this topic for only the second time.

Third, this project furthers our knowledge by combining well-designed measures of breastfeeding with robust measures of contraceptive use. In the public health literature, few data sets capture both breastfeeding and contraceptive use and even fewer do it with measures that are well designed to address these research questions. The Purple Crying data set is unusual in both ways, and therefore offers a special opportunity to explore the biological interaction between the two.

Finally, this project is innovative in its exploration of social, demographic and healthcare factors and their relationship to the interaction between breastfeeding and contraceptive use. A thorough understanding of the interplay of these issues is important for understanding how to improve outcomes, diminish health disparities, and enable women to make informed choices about their lives. This project seeks to elucidate the highest impact opportunities, as well as the places where further study is needed. In summary, this project innovates by examining the topic in a culturally relevant setting, applying novel methods, combining robust measures, and exploring the associated factors.

CHAPTER II: FACTORS ASSOCIATED WITH BREASTFEEDING DURATION IN A NORTH CAROLINA POPULATION

INTRODUCTION

Breastfeeding is the optimal form of infant feeding according to both the World Health Organization (WHO) and the American Academy of Pediatrics (AAP). (1,2) The health benefits of breastfeeding are well established with short and long term advantages for the baby and mother substantiated in the research literature. (3) Breastfed infants have lower rates of a wide range of illnesses including ear infections, bacterial meningitis, urinary tract infections, intestinal infections, diarrhea, and childhood cancers. (7-15) Lower rates of sudden infant death syndrome, asthma, obesity, and diabetes are seen in children who are breastfed. (16-24) Childhood cognitive development may also be enhanced by breastfeeding. (25-27)

Mothers experience better immediate and long-term health outcomes with breastfeeding. Women who breastfeed have less postpartum blood loss and are more likely to experience rapid uterine involution. (28) They also have lower rates of breast and ovarian cancer and fewer hip fractures and osteoporosis later in life. (29-33) The impact on long-term health for individuals and on healthcare costs as a nation is, therefore, large. (34) Infant morbidity and mortality related to the low prevalence of meeting the 6 month exclusive breastfeeding recommendations of the American

Academy of Pediatrics alone is estimated to cost the United States (US) $13 billion annually. (35)

The AAP and WHO recommend exclusive breastfeeding for the first six months of life with continued breastfeeding afterwards. The Healthy People 2010 initiative of the US Department of Health and Human Services set a goal for the country of at least 75% breastfeeding initiation and at least 50% breastfeeding continuation at 6 months. (4) By 2010, 76.9% of infants had ever been breastfed and 47.2% were nursing at six months, nearly meeting the Healthy People 2010 target. (5) However, only 16.3% were breastfeeding exclusively at six months, the recommendation from both the WHO and AAP. Healthy People 2020 set new goals for breastfeeding over the current decade including an 81.9% initiation rate, 60.6% continuation at six months, and 25.5% exclusive breastfeeding at six months. (6) To meet these ambitious targets new programs and policies will be needed.

This project aims to inform that process by providing up-to-date information about breastfeeding in a US population. North Carolina offers an ideal setting for this work because it falls in the middle of the spectrum of US states in terms of breastfeeding outcomes, has a diversity of urban and rural areas, and has significant immigration from other parts of the country, mixing social norms from other regions. Geophysically, socio-culturally and economically, there is a diversity of settings within the state that encompass a wide spectrum of the American social context. Politically, the electorate splits closely between major parties. There is a sizable minority of African Americans and Hispanics. Together, this makes North Carolina an informative setting to explore the current state of breastfeeding in the US, and well suited to addresses this question.

MATERIALS AND METHODS

Subjects

North Carolina birth certificate records were used to identify English- and Spanish-speaking new mothers for a one-time telephone survey. Women were selected from the approximately 130,000 live births annually in the state. Potential study subjects were selected in four rounds with over-sampling for Hispanic maternal ethnicity, baby's age (<2 months, 2-3 months), size of the hospital where the mother gave birth, and urban/rural location. Once selected, the mother's telephone number was back-matched from name and address information on the birth records, and only those records for which a telephone number could be matched and for whom a household in North Carolina could be reached were considered eligible for study participation by the study sponsors. Unless there was more than one eligible child in the household, no effort was made to verify that the study participant matched the infant referenced on the birth certificate. The female parent or legal guardian was interviewed one time, and interviews were conducted between April 2010 and March 2011. The complete sample included 1,669 women, while the study sample was restricted to participants with complete information on all study variables included in the analysis, leaving 1,573 respondents or 94.2% of the original sample.

STATISTICAL ANALYSES

Chi square and Wilcoxon rank sum tests were performed to assess differences between those who initiated breastfeeding and those who did not. Cox proportional hazards models using the discrete method were used to examine the association between the independent variables and breastfeeding duration, with time measured in weeks. Two analyses were performed. The first analysis included the entire study population, regardless of whether they initiated breastfeeding. This enabled us to examine the associations for the general population of women giving birth in this setting. The second analysis was among only those women who initiated breastfeeding, allowing us to explore the associations of timing of initiation, as well as, other independent variables with breastfeeding duration among initiators. Women who were still breastfeeding at the time of the interview were right censored in our analysis, whereas those who had ceased to breastfeed prior to the interview had a known, final breastfeeding duration. The final model was developed beginning from a full model that included all possible covariates known from the literature to be associated with breastfeeding outcomes and which were available in the sample. To assess the best way to code variables where more than one logical option existed, nested models were compared using likelihood ratio tests with a cut-off of $p<0.05$. Non-nested models were compared using Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC), and covariates that were neither statistically significant at the $p<0.05$ level nor crucial factors from the literature were removed from the model. A final, reduced model is presented here. All analyses were performed using SAS software version 9.2.

MEASURES

Demographic characteristics. Maternal age, infant race/ethnicity, region of birth, maternal educational attainment, and the baby's gender were assessed via the survey questionnaire. The BIC was used to determine that maternal age could be sufficiently modeled as a continuous variable as opposed to an ordinal variable with 5-year bins or with a quadratic term. Maternal age was mean-centered for ease of interpretation. Race/ethnicity of the infant was determined based on the mother's response to separate questions about race and Hispanic ethnicity. Participants could choose as many categories of race as they wished. A single category of race/ethnicity was used for the analyses and was coded to be the most conservative estimate of breastfeeding impact based on breastfeeding rates in the general population. If Hispanic ethnicity was indicated, it was chosen over other racial and ethnic categories. Infants with only one race reported on the survey were identified as that race. Among the remaining study subjects who were reported to be mixed-race, any infant identified as being "white" in a separate question about whether the parent considered the child white, was identified as "non-Hispanic white." Next, those who were reported to be mixed-race with one race being black were identified as "non-Hispanic black." All remaining study subjects were classified as, "other," which included Asian, Pacific Islander, Hawaiian, Alaskan native, and Native American, as well as, anyone who identified their child as "other".

Health factors. Particular health factors related to breastfeeding initiation and duration were assessed by specific questions in the interview. Nulliparous or multiparous status was determined based on the mother's response to whether there was an older biological sibling. Neonatal intensive care unit (NICU) stay for the infant was also directly queried in the interview.

Psychosocial factors. An aim of this study was to assess whether pregnancy wantedness is associated with breastfeeding outcomes. The wantedness of the pregnancy has been shown to affect other outcomes such as antenatal care, stunting and later mental health for the child, signs that care giving may be different for infants born of unwanted or mistimed pregnancies. (179-181)Moreover, pregnancy intention was shown to be associated with breastfeeding initiation and duration for white mothers in a US-based study from 1995. (182) Pregnancy intention was assessed using the World Health Organization's four part scale: wanted at this time, wanted not at this time, not wanted, and all pregnancies are wanted. The impact of a mother's intention to breastfeed was also explored via a direct question about her pre-birth intention to breastfeed.

Hospital practices. The Ten Steps to Successful Breastfeeding have been shown to impact both initiation and duration of breastfeeding in other populations (Table 2). (199) Mothers in this sample were asked about the seven practices that derive from the Ten Steps and that apply to the immediate postpartum time frame. A likelihood ratio test was used to inform the modeling of timing of initiation. Time points that would be informative to current recommendations and practices were also considered in developing

four categories of timing of breastfeeding initiation for our model. Provision of a hospital sample bag was modeled as a dichotomous variable (yes/no) that was considered independently from the other practices because many hospitals in this region implement this practice secondary to a statewide campaign. (210) The other 5 hospital practices were explored individually and as a proxy variable, scored zero to five, of how many of the practices were experienced by the mother. The practices were not specific to the Ten Steps, but are aspects of specific steps. These practices are immediate skin-to-skin contact between mother and infant after birth (Step 4), rooming-in at least 22 of every 24 hours (Step 7), visit by a Lactation Consultant (LC) or breastfeeding support person (proxy for Step 5), observation of a feeding by an LC or breastfeeding support person (also Step 5), and all facility staff supporting the mother's decision on infant feeding (also Step 5).

Breastfeeding. The outcome of interest, breastfeeding duration, was determined based on three questions from the interview. At the beginning of the interview, mothers were asked the birth date of their infant, and the infants age at the time of the survey was calculated from the difference between the interview date and the infant's birth date. Later, respondents were asked whether they were still breastfeeding their infant, and if not, a follow-up question was asked about the age at which they ceased breastfeeding their infant. About 70% of the respondents were still breastfeeding at the time of the survey, and their breastfeeding duration was right censored in the analysis. Among those who reported having stopped breastfeeding, their breastfeeding duration was calculated based on the mother's report of the infant's age at cessation. This was compared to the actual

infant's age at the time of the survey, and implausible values due to impossible

relationships between the times reported were discarded as unreliable; however, no

subjects were dropped due to implausible values for infant age.

Interaction Terms. An exploratory analysis of interactions between the factors in the

model was performed by modeling interaction terms between the variables for hospital

practices and maternal age, timing of breastfeeding initiation, NICU stay, infant gender,

intention to breastfeed. In addition, interaction terms for first born status and NICU stay

and for the wantedness dummy variables were explored, as well as breastfeeding

intention and infant gender since breastfeeding duration has been shown in some studies

to be associated with infant gender. A statistically significant interaction between NICU

stay and parity was found for one of our analyses. In the other analysis, its significance

diminished beyond the p< 0.05 level when other factors were included in the model. An

interaction between maternal age and the hospital practices proxy variable was also

found, and it was significant in some analyses at the p<0.05 level. A likelihood ratio test

and the BIC were used to inform the final selection of the ordinal hospital practices

variable for the model.

Missing Data. With the exception of the variables for household income (10.7% missing)

and intended duration of breastfeeding (17.8% missing), the level of missing data in this

sample was very low, between 1% and 3% for all variables. A likelihood ratio test was

carried out for the model with and without household income, and it was determined that

household income was not critical for the model. Forest plots were used to assess whether

estimates of the other variables were affected by including or excluding income, and in no case did the change in parameter estimate exceed the confidence interval for that variable. Likewise, the high degree of missing data for intended breastfeeding duration was thought to be non-random, potentially representing differences in confidence, determination, and/or education about breastfeeding that could be reflected by having an intended duration or not having a clearly defined plan for this. Therefore, both income and intended breastfeeding duration were excluded from the model. A complete case analysis was performed, excluding respondents with missing values for any variables, which led to a final study sample of 1,573 (94.2% of the original 1,669 respondents).

IRB. This study received IRB approval from the University of North Carolina, Chapel Hill.

RESULTS

Description of the population by Univariate and Bivariate Analyses

The sample included 1,573 women for whom there was complete information on all variables in the analysis (Table 3). Most of these women initiated breastfeeding (1,333), with only 15.3% not initiating after birth (Tables 5a and 5b). The mean maternal age in the population was 30.2 years old, with a minimum of 14 and a maximum of 46 (Table 5a). The sample was 65.9% non-Hispanic white, 12.5% non-Hispanic black, 18.7% Hispanic, and 2.9% other. There were slightly more female infants (51.9%), and 11.6% of infants spent time in the NICU in comparison to about 6.7% nationally. (211)

87

First time mothers made up 64.5% of the population and 12.3% of women had less than a high school degree, 29.1% had a high school education, 40.0% had a college degree, and 18.6% had a graduate degree. The mean infant age at the time of the interview was 3.52 months (Table 5a), and across the range of infant ages there was variation in whether or not the mother-baby dyad was still breastfeeding (Table 4).

Significant differences on most variables existed between women who initiated breastfeeding and those who did not (Tables 5a and 5b). While the minimum and maximum ages of these groups were nearly identical, minimum of 14 for both, and maximum of 46 and 45 respectively, the median age of those who ever breastfed was 31, whereas those who never breastfed had a median age of 29. Race/ethnicity was also significantly different between the groups who did and did not breastfeed. Blacks were much less likely to breastfeed than other groups, with 67.5% breastfeeding. Hispanics were much more likely to breastfeed; fully 92.9% initiated breastfeeding. Whites and those classified as other had nearly equal breastfeeding initiation rates, 85.6% and 86.7% respectively. Mothers with more education were more likely to initiate breastfeeding, with the least likely being those with only a high school degree (75.5%), followed by mothers with less than a high school education (81.4%), and mothers with a college degree (87.0%). Nearly all women with a graduate degree initiated breastfeeding (96.6%). Timely, wanted pregnancies were more likely to be followed by breastfeeding initiation (88.0%), than mistimed and unwanted pregnancies (79.6%) or for women for whom 'all pregnancies would be wanted' (80.7%).

Intention to breastfeed was strongly associated with breastfeeding initiation, but doesn't appear to be absolutely necessary for initiation or to guarantee initiation. A

88

notable group of women who had not intended to breastfeed did initiate (15.9%), and a smaller group who had planned to breastfeed never initiated (5.5%).

Women's experience with breastfeeding-related maternity care practices is also significantly different between those who initiate and those who do not. Formula sample bag were received at hospital discharge by 87.9% of women who did not breastfeed, whereas 76.4% of women who initiated breastfeeding received one. Among women who initiated breastfeeding, 44.4% started within the first hour after giving birth, 20.1% started between one and two hours, 25.4% started between 2 and 24 hours, and 10.1% started after the first day (Table 6). Five other maternity care practices were combined into a proxy variable for the number of breastfeeding-supportive hospital practices experienced by women in our study, and the association with breastfeeding initiation was significant for this composite measure. While the minimum and maximum were the same, zero and five respectively, the median number of practices experienced by those who did not initiate was two, compared to four practices for those who did breastfeed. All five of the individual practices that comprised this proxy variable were also significantly different between those who ever breastfed and those who did not.

The infant's gender, whether he or she was the first-born, and whether he or she had been admitted to the NICU were not significantly different between those who initiated breastfeeding and those who did not, though the trends on each of these characteristics are in keeping with results from other studies showing lower breastfeeding rates for boys, infants in the NICU, and first babies.

Multivariate Analysis of Factors Associated with Breastfeeding Duration for All Mothers

In a Cox proportional hazards model of time to breastfeeding cessation including all mothers in our sample, breastfeeding duration was significantly associated with race/ethnicity, maternal education, firstborn status, mother's intention to breastfeed, receipt of a formula sample bag, and an interaction between maternal age and hospital practices (Table 7). Maternal age, pregnancy wantedness, the baby's gender, the number of hospital practices experienced, and an interaction between NICU stay and first-born status did not predict breastfeeding duration in this model.

Blacks had the highest odds of breastfeeding cessation (OR 1.35, 95% CI 1.05 – 1.07), while Hispanics had the lowest (OR 0.55, 95% CI 0.42 – 0.72). Maternal education was associated with breastfeeding duration in a dose response manner. Compared to mothers with a high school education, the odds of breastfeeding cessation among college-educated women were 45% lower (OR 0.55, 95% CI 0.39 – 0.77), and among women with a graduate degree were 67% lower (OR 0.33, 95% CI 0.22 – 0.50). First-born infants had higher odds of breastfeeding cessation than infants with multiparous mothers (OR 1.46, 95% CI 1.19 – 1.79). That is, mothers who had older children were less likely to stop breastfeeding than first time mothers. Intention to breastfeed was highly associated with breastfeeding continuation (OR 0.08, 95% CI 0.06 – 0.10). Hospital policies were also significantly associated with breastfeeding outcomes. Receiving a formula sample bag at hospital discharge was associated with an increased in the odds of cessation (OR 1.80, 95% CI 2.44 – 2.26). Hospital practices were not significantly associated with breastfeeding duration, but an interaction term for hospital practices and maternal age was significantly associated (OR 0.99, 95% CI 0.98 – 1.00).

That is, for each 1-year increase in maternal age and one practice increase in the number

of hospital practices received, there was a 1.3% decrease in the odds of breastfeeding

cessation

Survival curves of breastfeeding duration (figure 4) were drawn showing the

variation of a single variable. All other covariates held constant at their mean value from

the regression model: Firstborn (0.35), NICU (0.12), interaction term for NICU and

firstborn (0.05), black race/ethnicity (0.13), Hispanic race/ethnicity (0.19), other

race/ethnicity (0.03), unwanted or mistimed pregnancy (0.26), all pregnancies wanted

(0.14), maternal age (7.4×10^{15}), high school education (0.29), college education (0.40),

graduate school education (0.19), intention to breastfeed (0.88), infant gender (0.52),

receipt of a formula sample bag (0.78), hospital practices (3.67), interaction term for

hospital practices and maternal age (110.41).

Multivariate Analysis of Factors Associated with Breastfeeding Duration Among Those Who Initiate Breastfeeding

Among women who initiated breastfeeding, the predictors of breastfeeding

duration in a multivariate analysis using a Cox proportional hazards model were

race/ethnicity, education, pregnancy wantedness, first-born status, an interaction between

NICU stay and first-born status, intention to breastfeed, receipt of a formula sample bag,

and timing of initiation (Table 8). All statistically significant associations were smaller

when the analysis sample was limited to those who initiated, with the exception of those

women who had a graduate school education, which was larger here (OR 0.49, 95% CI

0.31-0.76). In addition, the interaction term for maternal age and hospital practices is not

91

statistically significant in this sub-population, although it was marginally significant for all mothers.

Two factors were significant here but not in the large sample, pregnancy wantedness and an interaction between NICU stay and first-born status. Women with mistimed or unwanted pregnancies had higher odds of breastfeeding cessation than women with timely, wanted pregnancies (OR 1.32, 95% CI 1.06-1.65). An interaction between NICU stay and first-born status is associated with longer breastfeeding duration among infants with older siblings who spent time in the NICU relative to first-born infants who had NICU stays (OR 0.56, 95% CI 0.32 – 0.97). In this sub-population of only those who initiate breastfeeding after birth, the significance of differences in breastfeeding outcomes for blacks relative to white (OR1.11, 95% CI 0.85-1.47) and for college-educated relative to less educated women (OR 0.74, 95% CI 0.51-1.07), which was observed in the analysis of all mothers, disappeared.

Timing of initiation is also associated with breastfeeding duration; initiation within the first hour is associated with longer durations. Compared to those who initiate within the first hour, those who initiate between the first and second hour have a 43% higher odds of cessation (OR 1.43, 95% CI 1.10 – 1.85), and those who initiation later in the first day have a 80% higher odds of cessation (OR 1.80, 95% CI 1.42 – 2.29). Those who initiate after the first day have 62% higher odds of cessation compared to those within the first hour (OR 1.62, 95% CI 1.13 – 2.32).

Survival curves of breastfeeding duration for women who initiate breastfeeding (figure 5) were drawn showing the variation of a single variable. All other covariates held constant at their mean value from the regression model: First-born (0.36), NICU

92

(0.11), interaction term for NICU and firstborn (0.05) Black race/ethnicity (0.10), Hispanic race/ethnicity (0.21), other race/ethnicity (0.03), mistimed/unwanted pregnancy (0.25), all pregnancies wanted (0.13), maternal age (4.9×10^{15}), high school education (0.26), college education (0.41), graduate school education (0.21), intention to breastfeed (0.98), baby's gender (0.52), breastfeeding initiation between 1 and 2 hours (0.20), breastfeeding initiation between 2 and 24 hours (0.25), breastfeeding initiation after 24 hours (0.10), receipt of a formula sample bag (0.76), hospital practices (3.88), interaction term for hospital practices and maternal age (117.28).

DISCUSSION

A Cox proportional hazards model of time to cessation of breastfeeding for all mothers in the sample found race/ethnicity, maternal educational attainment, having one's first biological child, intention to breastfeed and an interaction term for maternal age and the number of hospital practices experienced by the mother to be significantly associated with breastfeeding duration.

Racial and ethnic differences in breastfeeding outcomes found in this study are consistent with national trends. Hispanics have the highest initiation and continuation rates, followed by whites and then blacks whose initiation rate lags whites by nearly twenty percentage points. This striking racial health-behavior disparity may be a foundation for other health disparities since breastfeeding is associated with a reduction in many infectious and chronic diseases. In terms of breastfeeding, race may serve in part as a proxy for a variety of socioeconomic and cultural factors that define distinct

contexts for breastfeeding. In order to improve breastfeeding outcomes for black mothers, identifying and addressing their specific barriers to breastfeeding will be important. In this study, breastfeeding durations for the sub-population of women who successfully initiate breastfeeding did not differ for black and white mothers. This suggests that achieving breastfeeding initiation is critical in addressing the lower breastfeeding rates among blacks, and that once over this hurdle, breastfeeding outcomes are similar to those of whites. In light of this, efforts to reduce health inequity based on lower breastfeeding rates for blacks should be targeted at increasing breastfeeding initiation in this group.

Breastfeeding duration was nearly identical for mothers with high school degrees and those who had not completed high school, but there seemed to be a dose-response effect for higher levels of education. Similar to the results for race, the difference in breastfeeding duration between college educated mothers and those with less education disappeared in the analysis that included only those who had initiated breastfeeding, implying that the positive association with being college educated primarily affects breastfeeding initiation. Women with a graduate degree, however, continued to have a significantly lower risk of breastfeeding cessation even after accounting for differences in initiation. Maternal educational is often considered a proxy for socioeconomic status; however, in this instance it may be capturing additional dimensions relevant for breastfeeding outcomes, such as increased knowledge of breastfeeding, maternal self-efficacy, ability to seek and obtain support, differences in partnership dynamics, economic power within the family, and differences in decision-making responsibility, among many other possible explanations. Further, highly educated women may be more

94

likely to have work environments that are conducive for breastfeeding, have access to maternity leave, or be able to choose not to work. Identifying the factors that contribute to the better outcomes among these mothers could inform policies and programs to help meet the national breastfeeding continuation goals.

Mothers with timely, wanted pregnancies were most likely to begin breastfeeding, while all others initiated at similar, lower rates. Pregnancy wantedness was significantly associated with duration among those who initiated breastfeeding. This factor – wantedness of the pregnancy - is not generally included in the US-based studies however in this study there is a suggestion that those who successfully control fertility may also have increased success in the health and parenting choices made after birth. This further highlights the importance of a woman's ability to access effective and attractive contraception not only for the mother's health outcomes, but also for those of her child. Conversely, a possible confounder could be that access to both fertility control and breastfeeding are the result of access to adequate health care. Since birth spacing contributes to both maternal and child health, and since there is an association in this study between fertility control and breastfeeding success, further study of this issue in the US context is warranted.

First time mothers were found to breastfeed for shorter durations, on average, compared to mothers with older biological children. While this is a not uncommon finding in the literature, in this study there is an interaction between infant NICU stay and first-born status, showing a lower risk of breastfeeding cessation among first time mothers whose baby spends time in the NICU. This is somewhat counter-intuitive, because the infants in these mother-baby dyads are less healthy than their peers. Since

the improved breastfeeding outcomes are unlikely to be attributable to infant factors, this suggests that, for first-time mothers, interaction with the NICU is beneficial for breastfeeding. At least one older study based on national datasets found that prolonged infant stay in the hospital was associated with increased breastfeeding duration. (212) Future studies could explore this situation to see if there are factors that might modeled as healthcare practices to promote breastfeeding for all first-time mothers.

Intention to breastfeed was strongly associated with breastfeeding duration. The magnitude of this association suggests that program or clinical activity designed to influence women's breastfeeding intention may be a high-yield opportunity for improving breastfeeding outcomes. Hence, there may be a need for health education campaigns aimed at women and their families before conception or early in prenatal care, instead of at the end of their pregnancies. In bivariate analyses, intention to breastfeed was highly associated with initiation, but not completely predictive. About 5.5% of women who intended to breastfeed did not initiate; this may have been due to adverse experiences during or immediately following labor and delivery, such as maternal or infant illness, hospital practices or other events that interfered with initiation. On the other hand, 15.9% of women who had not planned to breastfeed nonetheless initiated breastfeeding. From a breastfeeding advocacy standpoint, these changes from original intention suggest that experiences around the time of birth can affect breastfeeding outcomes. Such impact of the hospital experience on breastfeeding outcomes is illustrated in the extensive literature on hospital practices that serve as barriers to breastfeeding. (213) A higher percentage of women were converted from non-intention to breastfeeding than the other direction, and this may indicate that activities ongoing in

NC hospital settings are reflected in breastfeeding support. This hypothesis is supported by the fact that those who initiated breastfeeding reported more of the Ten Step hospital practices that are known to be associated with breastfeeding initiation in other settings. (199)

The Ten Steps to Successful Breastfeeding guidelines were developed by UNICEF and WHO to provide guidance for clinicians providing obstetric and maternity care regarding practices that support a mothers' ability to succeed in breastfeeding initiation and achieve longer durations of breastfeeding. Seven of these steps related to maternity care practices around birth and the immediate postpartum time frame. Women who received a formula sample bag, part of Step 6, were less likely to initiate breastfeeding than those who did not receive a sample bag. Because initiation comes before the sample bag would be offered, this could reflect a lack of system-wide support for breastfeeding. This study confirmed that receipt of formula sample bags is associated with shorter breastfeeding duration. Having formula on-hand may provide an easy "solution" during breastfeeding challenges, and creates a path to feeding supplements, which can disrupt the physiology of milk supply and lead to weaning. Another explanation for this association may be that formula sample bags could be a proxy for a number of other, unmeasured practices and interactions that either discourage breastfeeding or pre-dispose it to be of shorter duration, as suggested by the association with breastfeeding initiation. In North Carolina, the setting for this study, efforts by the North Carolina Breastfeeding Coalition (NCBC) to encourage hospitals not to provide these bags in North Carolina have resulted in hospitals eliminating formula sample bags as a first step, and this may or may not be the only, clearly defined change to

97

breastfeeding-related maternity practices. (210) Thus, stopping provision of formula sample bags may be an early marker that a hospital is moving towards more breastfeeding friendly policies.

Initiation of breastfeeding within the first hour after birth, as per Step 4 of the Ten Steps, is significantly associated with breastfeeding duration. Relative to early initiation, all later time points, including initiation between the first and second hours, were associated with significantly shorter duration of breastfeeding, and none of these later times of initiation were significantly different from each other. This supports the concept that there may be a critical window for breastfeeding initiation and further supports the contention that hospital policies for delivery practices may have a long-term impact on breastfeeding.

The five other hospital practices evaluated in this study were immediate skin-to-skin contact after birth, infant rooming-in, visit by a lactation consultant or other breastfeeding support person, observation of a feeding by a lactation consultant or other breastfeeding support person, and whether the mother felt supported in her feeding choice by all facility staff. The mean number of practices reported by women who initiated breastfeeding was 3.9, in contrast to only 2.5 for women who did not begin nursing. Individually, all five practices were also significantly associated with breastfeeding initiation, confirming that the maternity care practices endorsed in the Ten Steps are positively associated with this measure of breastfeeding success. While there was a trend towards positive associations with breastfeeding duration, this association was not statistically significant. This could indicate that other factors have a bigger impact on longer-term breastfeeding outcomes. Recall bias or confusion with the survey questions

could also be an issue. Nonetheless, all seven of the Ten Step hospital practices evaluated in this study were found to have a significant association with breastfeeding outcomes, adding evidence that these measures are relevant and worthwhile for breastfeeding promotion in the current US maternity care setting. This has important implications for public health policy and for best practices for clinical care. This work further substantiates that implementation of the Ten Step guidelines could improve breastfeeding outcomes in the US and should be strongly considered by policy-makers.

Finally, an interaction term between maternal age and the number of hospital practices reported by the mother shows a protective effect that increases with both maternal age and the number of breastfeeding supportive hospital practices a woman receives. This result should be interpreted with caution since it is only marginally significant at the $p<0.05$ level and since neither factor on which it is based is, by itself, significantly associated with breastfeeding duration in the multivariate analysis. On the other hand, both maternal age and hospital practices have been associated with increased duration of breastfeeding in other studies, so it is plausible that these factors could play a role in breastfeeding success. While the odds ratio appears to be small, just 1.3% lower odds per maternal year and hospital practice, the impact can quickly add up when one considers maternal ages of 20, 30 or 40 years, and multiple hospital practices. The implication of this term, if valid, is that hospital practices affect older mothers differently than younger ones. Further research is needed to clarify whether this effect is spurious, but to the extent that it reflects real differences among mothers, it has important implications for the implementation of breastfeeding-related hospital practices and for improving health disparities between mothers of different ages.

LIMITATIONS

The high amount of censored data in this sample (69.0%) may limit the power to detect differences in breastfeeding duration. While their ultimate duration of breastfeeding is unavailable for these women, it is informative that they were able to breastfeed as long as they reported. Censoring would likely be a less significant issue at earlier time-points, which is the time frame of most interest since women may be a more vulnerable to breastfeeding cessation as the biology and behavior of breastfeeding are being established. Censoring could bias the sample if it were associated with breastfeeding. This sample was selected at random from birth certificate data, limiting this possibility; however, if availability by landline telephone or willingness to participate in a telephone survey was correlated with breastfeeding outcomes or contraceptive use this could introduce bias.

Intensity or exclusivity of breastfeeding could not be evaluated in this sample, and therefore could not assess these more nuanced breastfeeding outcomes. This is unfortunate, since exclusivity is a relevant outcome of interest for behavioral, health, and policy reasons. In the United States, there is a large drop-off in breastfeeding rates during the first year, which could affect the ability of this study to detect associations between specific factors and breastfeeding outcomes. If unmeasured or poorly measured factors are more important to breastfeeding cessation than the factors examined here, it may be difficult to detect their impact on breastfeeding due to residual confounding.

Confounding is a particular problem in this area of work as seen by the significant demographic differences between those who did and did not initiate breastfeeding and by breastfeeding duration. Breastfeeding outcomes have been associated with many factors including demographic, social, psychological, health, and healthcare. This dataset is unusual for the number and quality of breastfeeding-related questions available. However, information on partnership status, social support for breastfeeding, maternal depression, urbanicity, maternal obesity, employment and others were not available in this dataset. To the extent that the factors available are more proximal to the outcome, they may serve as adequate proxies for these and other unmeasured factors and mitigate the vulnerability of this analysis to issues of confounding.

The sample population was selected from North Carolina Birth Certificates and contacted by telephone. Differences in the covariates and in breastfeeding outcomes may exist between those available by landline telephone and those who cannot be reached by this means including those who do not have a landline telephone. For instance, people who use cell phones exclusively would not be contacted in this study, and this could disproportionately exclude younger, poorer, and more transient mothers leading to sample bias. If willingness to participate in a telephone survey is not randomly distributed, the sample would also be biased. These concerns are addressed in two ways. First, the random selection process using birth certificate records provides an unbiased foundation for sample selection. In addition, many measures were undertaken to contact potential subjects including multiple contact attempts, contact at different times of the day and week, and contact attempts over several months. Furthermore, if the potential

participant declined, efforts were made by specially trained personnel to convince the potential study subjects to participate.

The retrospective study design relied on maternal self-report and is vulnerable to recall bias which would be more likely to affect transient factors and factors with perceived positive or negative connotation. For example, unwanted and mistimed pregnancies are reported less often in this sample than has been found in national data. Mothers may be reluctant to tell the interviewer that their pregnancy was unwanted or mistimed, and she might also unconsciously re-evaluate the wantedness of her pregnancy as she begins to bond with her baby. Similarly, a mother's recall of her intention to breastfeed may change in light of her actual experience of breastfeeding. Reporting of hospital practices may be also be bias by events that happen later, and mothers could simply not remember what occurred during that time. Some may not even know whether and when events happened, which could be correlated with maternal or infant health. Non-random missing data could also lead to sample bias, however the amount of missing data for the variables used in the model was 1%-3%, which is very low. This sample is likely comparable in these regards to other studies on breastfeeding since the results on covariates commonly reported in the literature are consistent with other breastfeeding studies.

CONCLUSION

Overall, these results highlight the importance of labor and delivery practices that allow and enable immediate breastfeeding initiation for long-term breastfeeding success.

These results support the importance of the Ten Steps to Successful Breastfeeding for breastfeeding duration, and suggest that greater adoption of and adherence to this standard could improve breastfeeding outcomes.

Table 2. The Ten Steps to Successful Breastfeeding, WHO/UNICEF
1. Have a written breastfeeding policy that is routinely
communicated to all healthcare staff
2. Train all healthcare staff in skills necessary to implement this policy
3. Inform all pregnant women about the benefits and management of breastfeeding
4. Help mothers initiate breastfeeding within a half-hour of birth
5. Show mothers how to breastfeed, and how to maintain lactation even if they should be
separated from their infants
6. Give newborn infants no food or drink other than breast milk, unless *medically*
indicated
7. Practice rooming-in—allow mothers and infants to remain together—24 h a day
8. Encourage breastfeeding on demand
9. Give no artificial teats or pacifiers to breastfeeding infants
10. Foster the establishment of breastfeeding support groups and refer mothers to them on
discharge from the hospital

Table 3: Characteristics of the sample (N=1,573) from a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11.

	Total	Percent of Total
	N=1573	100%
Race/Ethnicity		
Non-Hispanic White	1,037	65.9%
Non-Hispanic Black	197	12.5%
Hispanic	294	18.7%
Other	45	2.9%
Maternal Education		
Less than High School	194	12.3%
High School	457	29.1%
College	629	40.0%
Graduate School	293	18.6%
Pregnancy Wantedness		
Wanted at This Time	940	59.8%
Not Wanted / Mistimed	420	26.7%
All Pregnancies Wanted	217	13.8%

First Child			
	Yes	558	35.5%
	No	1,015	64.5%
Baby's Gender			
	Female	817	51.9%
	Male	756	48.1%
NICU Stay			
	no	1,390	88.4%
	yes	183	11.6%
Intended to Breastfeed			
	No	195	12.4%
	Yes	1,378	87.6%
Received Formula Sample Bag			
	No	343	21.8%
	Yes	1,230	78.2%
Immediate Skin-to-Skin			
	No	712	45.3%
	Yes	861	54.7%
Rooming-In			
	No	386	24.5%
	Yes	1,187	75.5%
LC Visit			
	No	423	26.9%
	Yes	1,150	73.1%
LC Observe Breastfeeding			
	No	484	30.8%
	Yes	1,089	69.2%
Staff Supported Mother's Decision			
	No	91	5.8%

Yes	1,482	94.2%

Table 4: Breastfeeding Status by Month Amongst Those Surveyed at that Time Point or Later (Total N=1,573). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11.

	Not Breastfeeding n (%)	Breastfeeding n (%)	Total n
1 Month	410 (26.1%)	1163 (73.9%)	1,573
2 Months	557 (35.9%)	993 (64.1%)	1,550
3 Months	624 (45.8%)	739 (47.0%)	1,363
4 months	297 (48.8%)	311 (51.8%)	608
5 Months	42 (58.3%)	30 (41.7%)	72
> =6 Months	27 (60.0%)	18 (40.0%)	45

Table 5a: Characteristics of the Population (continuous variables) by Breastfeeding Initiation From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11. (N=1,573).

	No Breastfeeding	Initiated Breastfeeding	Total
	N=240	N=1333	N=1573
Maternal Age (years)**			
Mean	29.2	30.3	30.2
Median	29	31	31
Infant Age at interview (months)			
Mean	3.78	3.47	3.52
Median	3	3	3

106

Hospital Practices***				
	Mean	2.5	3.9	3.7
	Median	2	4	4
*** p<0.001 ** p<0.01 * p<0.05				

	No Breastfeeding n (%)	Initiated Breastfeeding n (%)	Total n
Table 5b: Characteristics of the Population by Breastfeeding Initiation From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11. (N=1,573).			
	N=240	N=1333	N=1573
Race/Ethnicity*			
Non-Hispanic White	149 (14.4%)	888 (85.6%)	1,037
Non-Hispanic Black	64 (32.5%)	133 (67.5%)	197
Hispanic	21 (7.1%)	273 (92.9%)	294
Other	6 (13.3%)	39 (86.7%)	45
Maternal Education*			
Less than High School	36 (18.6%)	158 (81.4%)	194
High School	112 (24.5%)	345 (75.5%)	457
College	82 (13.0%)	547 (87.0%)	629
Graduate School	10 (3.4%)	283 (96.6%)	293
Pregnancy Wantedness*			
Wanted at This Time	113 (12.0%)	827 (88.0%)	940
Not Wanted / Mistimed	85 (20.4%)	331 (79.6%)	420
All Pregnancies Wanted	42 (19.4%)	175 (80.7%)	217
First Child			

	Yes	77 (13.8%)	481 (86.2%)	558
	No	163 (16.1%)	852 (83.9%)	1,015
Baby's Gender				
	Female	122 (14.9%)	695 (85.1%)	817
	Male	118 (15.6%)	638 (84.4%)	756
NICU Stay				
	no	205 (14.8%)	1,185 (85.3%)	1,390
	yes	35 (19.1%)	148 (80.9%)	183
Intended to Breastfeed***				
	No	164 (84.1%)	31 (15.9%)	195
	Yes	76 (5.5%)	1,302 (94.5%)	1,378
Received Formula Sample Bag***				
	No	29 (8.5%)	314 (91.6%)	343
	Yes	211 (17.2%)	1,019 (82.9%)	1,230
Immediate Skin-to-Skin*†				
	No	124 (17.4%)	588 (82.6%)	712
	Yes	116 (13.5%)	745 (86.5%)	861
Rooming-In**†				
	No	79 (20.5%)	307 (79.5%)	386
	Yes	161 (13.6%)	1,026 (86.4%)	1,187

LC Visit***†				
	No	177 (41.8%)	246 (58.2%)	423
	Yes	63 (5.5%)	1,087 (94.5%)	1,150
LC Observe Breastfeeding***†				
	No	187 (38.6%)	297 (61.4%)	484
	Yes	53 (4.9%)	1,036 (95.1%)	1,089
Staff Supported Mother's Decision***†				
	No	32 (35.2%)	59 (64.8%)	91
	Yes	208 (14.0%)	1,274 (86.0%)	1,482

*** p<0.001   ** p<0.01   *   p<0.05
† This variable is included in the ordinal "Hospital Practices" variable and is not included as a separate variable in the analyses.

Table 6: Timing of Breastfeeding Initiation For Women Who Initiated Breastfeeding, From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11.

	Percent in the entire sample (N=1,573)	**Percent among those who initiate (N=1,333)**
No Breastfeeding	240 (15.3%)	0 (0%)
< 1 Hour	592 (37.6%)	592 (44.4%)
1 to 2 Hours	268 (17.0%)	268 (20.1%)
2 to 24 Hours	339 (21.6%)	339 (25.4%)
Over 24 hours	134 (8.5%)	134 (10.1%)
Total	**1,573 (100%)**	**1,333 (100%)**

	Odds Ratio	Lower 95% Confidence Limit	Upper 95% Confidence Limit
Table 7: Parameter Estimates for the Cox Proportional Hazards Model of Time to Cessation of Breastfeeding for All Mothers (N=1,573). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11.			
Maternal Age	1.03	0.98	1.07
Race/Ethnicity*			
White	**referent**		
Black	**1.35***	1.05	1.72
Hispanic	**0.55***	0.42	0.72
Other	0.86	0.50	1.48
Maternal Education*			
Less Than High School	referent		
High School	0.99	0.74	1.32
College	**0.55**	0.39	0.77
Graduate School	**0.33***	0.22	0.50
Pregnancy Wantedness			
Wanted at this Time	referent		
Not Wanted / Mistimed	1.19	0.97	1.46
All Pregnancies Wanted	1.19	0.93	1.52
First Born	**1.46**	1.19	1.79
NICU Stay	0.99	0.72	1.37
NICU Stay x First Born	0.65	0.39	1.08
Baby's Gender	1.10	0.93	1.30
Intended to Breastfeed	**0.08***	0.06	0.10
Received Formula Sample Bag	**1.80***	1.44	2.26
Hospital Practices	1.19	0.85	1.67
Hospital Practices X	**0.99***	0.98	1.0

Maternal Age			

*** p<0.001   ** p<0.01   *   p<0.05

Table 8: Parameter Estimates for the Cox Proportional Hazards Model of Time to Cessation of Breastfeeding Among Those Who Initiate Breastfeeding (N=1,333). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11.

	Hazard Ratio	Lower 95% Confidence Limit	Upper 95% Confidence Limit
Maternal Age	1.01	0.95	1.06
Race/Ethnicity*			
White	referent		
Black	1.11	0.85	1.47
Hispanic	**0.58***	0.43	0.77
Other	0.81	0.44	1.49
Maternal Education*			
High School	referent		
Less than High School	1.12	0.82	1.54
College	0.74	0.51	1.07
Graduate School	**0.49**	0.31	0.76
Pregnancy Wantedness*			
Wanted at this Time	referent		
Not Wanted / Mistimed	**1.32***	1.06	1.65
All Pregnancies Wanted	1.15	0.87	1.52
First Born	**1.32***	1.06	1.65
NICU Stay	1.09	0.75	1.58
NICU Stay x First Born	**0.56***	0.32	0.97

Baby's Gender		1.18	0.98	1.42
Intended to Breastfeed		**0.38***	0.24	0.60
Received Formula Sample Bag		**1.66***	1.30	2.12
Hospital Practices		1.34	0.90	1.99
Hospital Practices X Maternal Age		0.99	0.98	1.00
Timing of Initiation*	< 1 Hour	referent		
	1-2 Hours	**1.43**	1.10	1.85
	2-24 Hours	**1.80***	1.42	2.29
	> 24 Hours	**1.62**	1.13	2.32
*** p<0.001 ** p<0.01 * p<0.05				

Figure 4: Survival Plots of Time to Cessation of Breastfeeding by Demographic Characteristics Among All Study Participants (N=1,573) From a survey evaluating the Period of Purple Crying intervention program, 2010-11. Curves show the variation of a single variable with all other covariates held constant at their mean value from the regression model: Firstborn (0.35), NICU (0.12), interaction term for NICU and firstborn (0.05), black race/ethnicity (0.13), Hispanic race/ethnicity (0.19), other race/ethnicity (0.03), unwanted or mistimed pregnancy (0.26), all pregnancies wanted (0.14), maternal age(7.4×10^{15}), high school education (0.29), college education (0.40), graduate school education (0.19), intention to breastfeed (0.88), infant gender (0.52), receipt of a formula sample bag (0.78), hospital practices (3.67), interaction term for hospital practices and maternal age (110.41).

Breastfeeding Duration
by Maternal Education

Breastfeeding Duration
by Firstborn Status

Breastfeeding Duration
by NICU Stay

% Still Breastfeeding

Breastfeeding Duration (Weeks)

NICU Stay   ▫▫▫ No NICU stay   ✱✱✱ Yes, NICU Stay

Breastfeeding Duration
by Baby's Gender

% Still Breastfeeding

Breastfeeding Duration (Weeks)

Baby's Gender   ▫▫▫ Female   ✱✱✱ Male

Breastfeeding Duration
by Breastfeeding Intention

% Still Breastfeeding

Breastfeeding Duration (Weeks)

Intended to Breastfeed   ▫▫▫ Yes   ✱✱✱ No

Breastfeeding Duration
by Receipt of Formula Sample Bag

% Still Breastfeeding

Breastfeeding Duration (Weeks)

Received a Formula Sample Bag at Hospital Discharge   ▫▫▫ Yes   ✱✱✱ No

Breastfeeding Duration
by Hospital Practices

% Still Breastfeeding

Breastfeeding Duration (Weeks)

Number of Hospital Practices Experienced by Mother ▫▫▫0 ✳✳✳1 △△△2
                                                    ⊙⊙⊙3 ▭▭▭4 ◇◇◇5

Breastfeeding Duration
by Pregnancy Wantedness

Breastfeeding Duration (Weeks)

Pregnancy Wantedness ▫▫▫ Wanted at This Time
                      ✳✳✳ Mistimed/Unwanted
                      △△△ All Pregnancies Are Wanted

118

Figure 5: Survival Plots of Time to Cessation of Breastfeeding by Demographic Characteristics among Women Who Initiated Breastfeeding (N=1,333) From a survey evaluating the Period of Purple Crying intervention program, 2010-11. Curves show the variation of a single variable with all other covariates held constant at their mean value from the regression model: First-born (0.36), NICU (0.11), interaction term for NICU and firstborn (0.05) Black race/ethnicity (0.10), Hispanic race/ethnicity (0.21), other race/ethnicity (0.03), mistimed/unwanted pregnancy (0.25), all pregnancies wanted (0.13), maternal age (4.9 x 10^{15}), high school education (0.26), college education (0.41), graduate school education (0.21), intention to breastfeed (0.98), baby's gender (0.52), breastfeeding initiation between 1 and 2 hours (0.20), breastfeeding initiation between 2 and 24 hours (0.25), breastfeeding initiation after 24 hours (0.10), receipt of a formula sample bag (0.76), hospital practices (3.88), interaction term for hospital practices and maternal age (117.28).

Breastfeeding Duration by Maternal Education

Breastfeeding Duration by Firstborn Status

120

Breastfeeding Duration by NICU Stay

Breastfeeding Duration by Baby's Gender
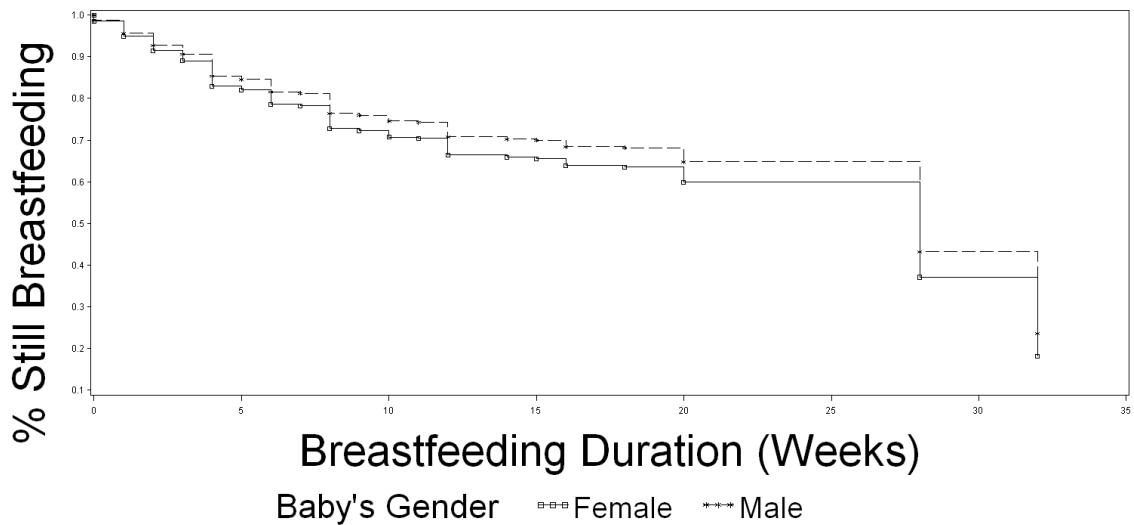
Breastfeeding Duration by Breastfeeding Intention
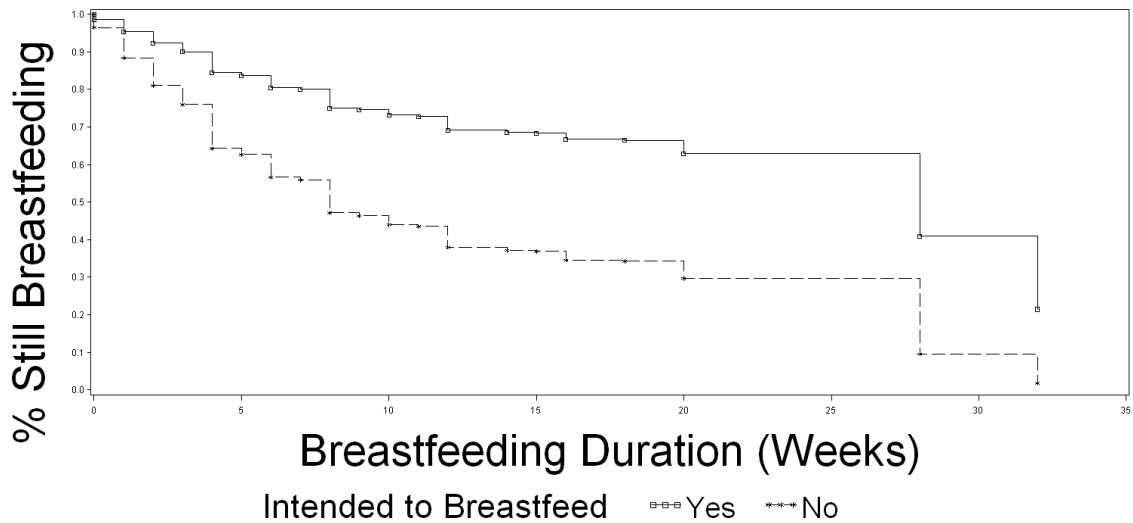
Breastfeeding Duration by Receipt of Formula Sample Bag
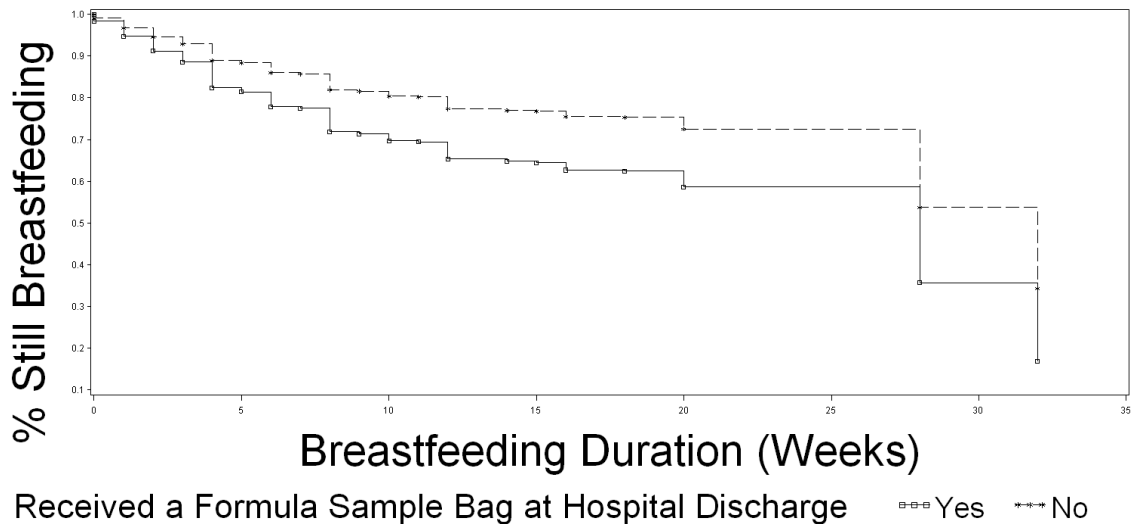
Breastfeeding Duration
by Timing of Breastfeeding Initiation
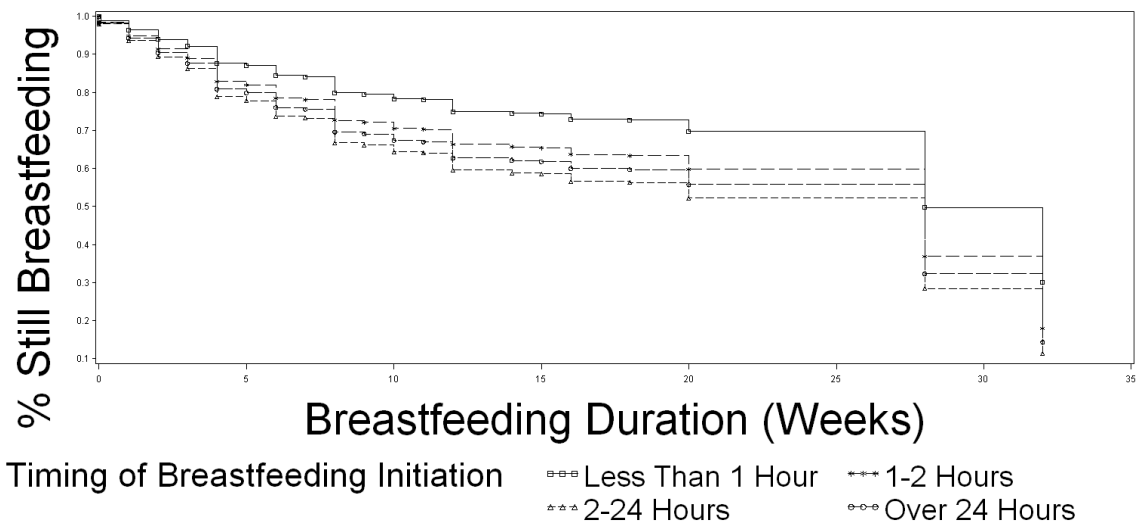
Timing of Breastfeeding Initiation   □□□ Less Than 1 Hour   +++ 1-2 Hours
                                          ▵▵▵ 2-24 Hours   ○○○ Over 24 Hours

Breastfeeding Duration
by Pregnancy Wantedness

Pregnancy Wantedness   □□□ Wanted at This Time
                           +++ Mistimed/Unwanted
                           ▵▵▵ All Pregnancies Are Wanted

123

Breastfeeding Duration by Hospital Practices

% Still Breastfeeding

Breastfeeding Duration (Weeks)

Number of Hospital Practices Experienced by Mother   0   1   2   3   4   5
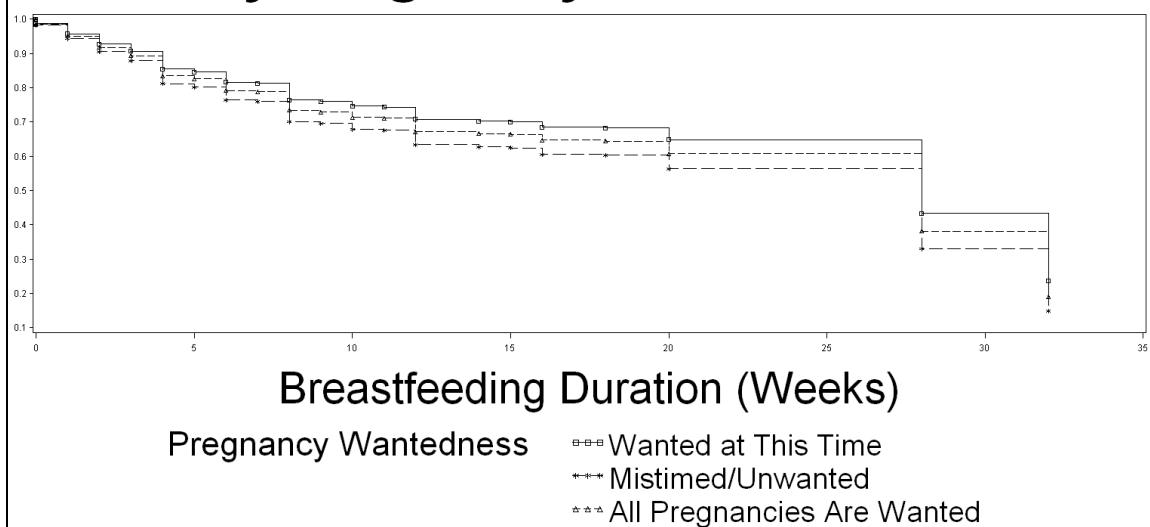
CHAPTER III: FACTORS ASSOCIATED WITH POSTPARTUM CONTRACEPTIVE USE AMONG BREASTFEEDING WOMEN

INTRODUCTION

Family planning has a major impact on the health of individuals and society. The International Conference on Population and Development (ICPD) in Cairo identified voluntary family planning as a central component of human rights and national development, emphasizing that family planning is one of the most cost effective ways to combat poverty. (214) But in spite of great improvements in the efficacy and availability of birth control, research funded by the Bill and Melinda Gates Foundation estimated that, as of 2009, more than 200 million women around the world lacked access to modern methods of contraception, and predicted that by 2050 this would increase by 40%. (36,37)

Many new methods of birth control have been developed in the US, and yet the number of unintended pregnancies remains high. The societal implications are large; Trussell et al. estimate that the annual cost of unintended pregnancy in the US is $4.5 billion. (41) In addition, racial and socioeconomic differences in the rate of unintended pregnancies represent a substantial health disparity, one that facilitates transfer of health and economic disparities to a new generation. Analysis by Finer and Henshaw showed that between 1994 and 2001, the rate of unintended pregnancy among white women was 35 per 1,000, while among black women it was 98 per 1,000 and for Hispanic women it

was 78 per 1,000. (39) Education is associated with the occurrence of unintentional

pregnancy, with 26 per 1,000 for women with college degrees, and 76 per 1,000 for

women without a high school degree. Contraceptive use follows similar racial and

education patterns and is thought to be both a response to and a cause of these

differences. (40)

A significant portion of this issue is postpartum contraception. (42)   About 100

million women around the world make decisions about postpartum contraception each

year, yet little attention is paid to understanding the particular priorities and needs of

women at this unique moment in their reproductive lives. (42) Accurate information,

specific to the health and social issues at this stage, is needed by women in the

postpartum as a foundation for informed decision-making.

Postpartum family planning is also important for public health since the length of

inter-birth intervals has serious implications for mother and baby. Women with short

birth intervals, less than six months, have a higher risk of maternal mortality (OR 2.54;

95% CI 1.22-5.38), third-trimester bleeding (OR1.73; 95% CI 1.42-2.24), premature

rupture of membranes (OR 1.72; 95% CI 1.53-1.93), puerperal endometritis (OR 1.33;

95% CI 1.22-1.45), and anemia (OR 1.30; 95% CI 1.18-1.43). (43) Among women with

previous Cesarean deliveries, birth intervals of less than 18 months are associated with a

higher risk of uterine rupture, 2.25% vs. 1.05% for intervals of 19 months or longer. (44)

It should be noted that the International Conference on Population and Development

(ICPD) in Cairo also emphasized the importance of breastfeeding for the health of the

mother and child. (214) Since the postpartum period is also the time-period when mothers

would be breastfeeding, effective pregnancy prevention that is compatible with breastfeeding is crucial to meeting both important health goals.

The Lactational Amenorrhea Method (LAM), a method of family planning based on the physiology of lactation, has been shown to be effective for up to the first six months for women who are breastfeeding according to the guidelines; however, many women prefer to use other contraception in the early postpartum period or require it when LAM no longer applies. (45-47) Accurate information about the compatibility of specific contraceptive methods with breastfeeding is needed for women to make informed choices about both family planning and breastfeeding.

The World Health Organization (WHO) and the American Academy of Pediatrics (AAP) concur that breastfeeding is the optimal form of infant feeding. (1,2) The health benefits of breastfeeding for both mother and baby are well established, with short and long term advantages substantiated in the research literature. (3) Breastfed infants have lower rates of a wide range of infectious, diseases, and chronic illnesses including ear infections, bacterial meningitis, urinary tract infections, intestinal infections, diarrhea, and childhood cancers. (7-15) Lower rates of sudden infant death syndrome, asthma, obesity, and diabetes are also seen in children who are breastfed. (16-24) Childhood cognitive development may also be enhanced by breastfeeding. (25-27)

Mothers experience better immediate and long-term health outcomes with breastfeeding. Women who breastfeed experience less postpartum blood loss and more rapid postpartum uterine involution. (28) They also have lower rates of breast and ovarian cancer and fewer hip fractures and osteoporosis later in life. (29-33) Therefore, the potential impact on long-term health for individuals and on healthcare costs as a nation is

127

large. (34) Infant morbidity and mortality related to the low prevalence of 6 months of exclusive breastfeeding is estimated to cost the United States $13 billion annually in pediatric costs alone. (35)

The AAP, WHO, and nearly all health professional organizations recommend exclusive breastfeeding for the first six months of life with continued breastfeeding thereafter as solids are introduced. (215,216) The Healthy People 2010 initiative of the US Department of Health and Human Services set national goals for breastfeeding initiation and continuation, but by 2010 only 16.3% of mother-baby dyads were breastfeeding exclusively at six months. (5) National breastfeeding targets were extended under Healthy People 2020, with new goals of 81.9% initiation, 60.6% continuation at six months, and 25.5% exclusive breastfeeding at six months. (4) To meet these goals, significant effort will be needed to further understand and address barriers to breastfeeding.

One area of controversy and confusion for mothers and clinicians is contraceptive use while breastfeeding, especially concerning the compatibility of hormonal contraceptive methods with breastfeeding. Clinical reports from lactation specialists indicate a negative impact of hormonal contraception on breastfeeding success, which contrasts with the recommendations in the Medical Eligibility Criteria for Breastfeeding (MEC) released by the Centers for Disease Control (CDC) in 2008, and updated in 2009 and 2013. These, guidelines maintain that these methods are safe to use during breastfeeding. This is in contrast with the most recent edition of the WHO MEC that is based on the same body of research evidence. (98-100,102)

This study aims to increase understanding of women's use of contraception in the postpartum period to inform the discussion of contraceptive use during breastfeeding in the early months postpartum. Much of the research underlying both the WHO and CDC recommendations was carried out in countries that have very different breastfeeding patterns than the US. Moreover, a substantial portion of this literature is more than 20 years old, raising the question of whether the contraceptive methods available at that time and the social context, for instance women's roles, attitudes towards breastfeeding, and awareness of the health implications of breastfeeding, are generalizable to the US today. This study, conducted in 2010-11 in North Carolina, addresses several social context issues and includes more current methods of contraception. North Carolina falls in the middle of the spectrum of US states in terms of breastfeeding initiation, has a variety of urban and rural areas, and has immigration from other parts of the country and beyond, mixing social norms from other regions. Geophysically, socio-culturally and economically, there is a diversity of settings within the state that encompass a wide spectrum of the American social context. Politically, the electorate splits closely between major parties. There is a sizable minority of African Americans and Hispanics. Together, this makes North Carolina an informative setting to explore the current state of breastfeeding in the US, and well suited to addresses the question of use of contraception in the postpartum period.

MATERIALS AND METHODS

Subjects

A survey of new mothers in North Carolina was carried out between April 2010 and March 2011. State birth certificate records were used to identify approximately 2,000 mother-baby dyads with infants about two to three months old. The mother's telephone number was then back-matched from name and address information on the birth certificate and attempts were made to contact her by landline telephone. Only those who had a valid telephone number that reached a residence in North Carolina were considered eligible for the study. Once contacted, the female parent or guardian was asked to engage in a one-time telephone interview in English or Spanish. Questions were specific to the infant in the household, and if more than one child was eligible for the survey, the child referenced on the birth certificate was the focus of the study. Otherwise, no additional check was made to verify that the interviewee corresponded with the person referenced on the birth certificate. Over-sampling was used to identify sufficient number of mothers of Hispanic ethnicity, babies of less than two months age and two to three months age, and to ensure a distribution of urban/rural participants, as well as, size of hospital at which the birth occurred. The sample included 1,669 study participants, of which 1,644 had completed interviews.

To look at the predictors of contraceptive use during breastfeeding in the postpartum period, the study population was limited to only those women who initiated breastfeeding, excluding 240 who did not (N=1,404). Finally, only participants with

complete information on all study variables were included in the analysis, leaving 1,319 respondents in the analytic sample or 93.9% of the eligible participants.

STATISTICAL ANALYSES

Chi square and Kruskal-Wallis tests were performed to assess differences in the distributions of covariates among users of each type of contraceptive in the postpartum period. Log binomial models were used to assess predictors of contraceptive choice after birth among women who breastfeed. To force convergence, a common weakness of the log binomial model, modified Poisson estimates were used as described by Spiegelman and Hertzmark (217) Women who used progestin-only methods were compared to those who used non-hormonal methods, and separately to those who used no method of contraception. Women who used combined estrogen/progestin methods were compared in separate analyses to those who used progestin-only contraception, non-hormonal contraception, and no form of birth control. To more readily interpret the results, the same covariates were modeled in each comparison.

Women who were breastfeeding at the time of the interview were right censored in our analysis, and actual durations were recorded for those who had ceased to breastfeed prior to the interview. The model was developed based on the literature and limited by the variables available in the dataset. To assess the best way to code variables where more than one logical option existed, nested models were compared using likelihood ratio tests with a cut-off of $p<0.05$. Non-nested models were compared using Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC), and

covariates that were neither statistically significant at the p<0.05 level nor crucial factors from the literature were removed from the model. Covariates that were significantly associated in any model were retained. A final, reduced model is presented here. All statistical analyses were performed using SAS software version 9.2.

MEASURES

Demographic characteristics. A variety of maternal and infant demographic data were obtained including the mother's age at the time of the survey, the mother's level of education, household income, the infant's gender and race/ethnicity, and the county in which the birth took place.

Maternal age was reported in years; a quadratic term and an ordinal variable with maternal age grouped by 5-year bins were explored, and the Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC) were used to determine whether the linear assumption of continuous coding was preferable for modeling the association. The mother's age was then mean-centered to enable more direct interpretation of the model. The survey included separate questions for Hispanic ethnicity and for race. Mothers could identify as many racial categories for their infant as they felt were applicable, and were asked whether they considered the child to be white. Infants identified as Hispanic ethnicity were recorded as Hispanic. Infants with only one race reported on the survey were identified as that race. Among the remaining study subjects who were reported to be mixed-race, any infant identified as being "white" in a separate question about whether the parent considered the child white, was identified as "non-

132

Hispanic white." Next, those who were reported to be mixed-race with one race being black were identified as "non-Hispanic black." All remaining study subjects were classified as, "other," which included Asian, Pacific Islander, Hawaiian, Alaskan native, and Native American, as well as, anyone who identified their child as "other".

The state of North Carolina has three primary regions, Western/Mountains, Piedmont, and Coastal Plain, which are used for programming, funding, and statistical tracking. Since there are differences among these regions in breastfeeding-related birth practices, as well as rates of initiation and duration of breastfeeding, the data on county in which the birth occurred were transformed into a variable for region of birth.

Health factors. Parity has been shown to be related to breastfeeding outcomes. A survey question asking whether there were older biological siblings of the child in the home. If there was a report of a biological older sibling, the subject child was considered to be born to a multiparous mother. Neonatal Intensive Care Unit (NICU) stay for the infant was asked on the questionnaire (yes/no).

Psychosocial factors. The mother's pregnancy and breastfeeding intention were assessed in the interview. Women were asked about their pre-birth intention to breastfeed (dichotomous yes/no) and intended duration. A high level of missing data for the intended duration question and strong co-linearity between these variables led us to choose the dichotomous variable for this study. It has been shown that pregnancy intention could also impact breastfeeding outcomes. (182) Outside of the US, pregnancy intention is a focus of work by the World Health Organization which classifies the

'wantedness' of a pregnancy in four categories: wanted at this time, wanted not at this time, not wanted, and all pregnancies are wanted. Mothers in this study were asked about their pregnancy intention using these same categories. Small cell-size led us to combine unwanted and mistimed pregnancies into one category of unwanted and mistimed pregnancies for the purposes of this analysis.

Hospital practices. Breastfeeding-related maternity practices were assessed by asking the mother to identify all of the breastfeeding-related maternity practices she had experienced during and after her birth. Receipt of a formula sample bag was explored on its own because evidence suggests that a substantial number of hospitals in North Carolina have stopped this practice without implementing the others. (210) These formula sample bags are thought to undermine breastfeeding success by providing an available alternative to breastfeeding. Recent work suggests that there may be a cumulative effect of breastfeeding-friendly hospital practices known as the Ten Steps. Therefore, the remaining five practices were explored individually and as a group using a proxy score, recorded as an ordinal variable (0-5), reflecting the total number of practices experienced by the mother. The practices derived from the Ten Steps, but are not exact reflections of any one specific step. These practices are immediate skin-to-skin contact between mother and infant after birth (from Step 4), rooming-in at least 22 of every 24 hours (from Step 7), visit by a Lactation Consultant (LC) or breastfeeding support person (proxy for Step 5), observation of a feeding by an LC or breastfeeding support person (also Step 5), and all facility staff supporting the mother's decision on infant feeding (also Step 5).

Postpartum contraceptive use. Study participants were asked which type(s) of contraceptive they used since the baby was born, and were allowed to identify as many types as applied. Contraceptives were then classified into four categories: no method, non-hormonal methods, progestin-only methods, and combined estrogen/progestin methods. Where multiple methods were reported, the woman's use was classified in the category thought to have the largest impact on breastfeeding, i.e., combined methods first, followed by progestin-only, non-hormonal and then no method.

Interaction terms. An exploratory analysis of interactions between variables was carried out in a separate analysis of direct associations between the independent variables and breastfeeding duration using a Cox proportional hazards model of breastfeeding cessation. Interactions between the variables for hospital practices and maternal age, timing of breastfeeding initiation, NICU stay, infant gender, and intention to breastfeed were tested. In addition, interaction terms for first-born status and NICU stay and for the wantedness dummy variables were explored, as well as breastfeeding intention and infant gender. An interaction between infant NICU stay and first-born status was found to be significant in some analyses, and was, therefore, kept in the model for all regressions. An interaction between the mother's age and a proxy for all hospital practices developed as an ordinal variable was significant and remained in the model. Interactions between the individual hospital practices and maternal age were also explored, and a likelihood ratio test was used to determine that the ordinal variable and ordinal variable-maternal age interaction term were the best for the model.

Missing Data. This data set included only 1%-3% missing data for all variables except intended duration of breastfeeding and household income, which were 10.7% and 17.8% respectively. A likelihood ratio test was carried out to determine that including household income in the model did not have a significant effect on the results. Forest plots were used to assess whether estimates of the other variables were affected by including or excluding income, and in no case did the change in parameter estimate exceed the confidence interval for that variable. Likewise, the high degree of missing data for intended breastfeeding duration was thought to be non-random, potentially representing differences in three factors: confidence, determination, and education about breastfeeding. Therefore, both income and intended breastfeeding duration were excluded from the model. The analysis included only those participants with complete data, i.e., a complete case analysis. The final study sample included 1,319 of the 1,404 respondents who were eligible for participation because they initiated breastfeeding.

IRB. This study received IRB approval from the University of North Carolina, Chapel Hill.

RESULTS

Description of the population

The sample included 1,319 women who had initiated breastfeeding and who also had complete information on all variables in the analysis (Table 9). The mean maternal

136

age in the population was 30.3 years old, with a minimum of 14 and a maximum of 46. The sample was 66.4% non-Hispanic white, 10.1% non-Hispanic black, 20.7% Hispanic, and 2.8% other. There were slightly more female infants (51.9%), and 11.2% of infants spent time in the NICU compared to about 6.7% nationally. (211) First time mothers made up 36.0% of the population and 11.9% of women had less than a high school degree, 26.2% had a high school education, 40.6% had a college degree, and 21.3% had a graduate degree. The mean infant age at the time of the interview was 3.29 months (Table 11a), and across the range of infant ages there was a distribution of breastfeeding status (Table 10). More women in this population used progestin-only methods of contraception at some time since birth (32.1%) than any other type of contraception (Table 11a). Non-hormonal methods were used by 29.9% of women, while 24.5% used no method, and 13.5 % used combined estrogen/progestin-methods of contraception.

When comparing users of different types of contraceptive methods in the postpartum period using bivariate analysis, statistically significant differences were found for maternal age, race/ethnicity, maternal education, first-born child, and visit by an LC or breastfeeding support person (Tables 11a and 11b). No statistically significant difference in pregnancy wantedness, baby's gender, infant NICU stay, intention to breastfeed, timing of initiation, receipt of a formula sample bag at hospital discharge, or the number of breastfeeding-related hospital practices received was found among contraceptive use categories.

Mean maternal age was different across categories of contraceptive use (Table 11a). The mean age for hormonal methods, either progestin-only (28.9) or combined

137

estrogen/progestin (28.5) was several years younger than for non-hormonal methods (31.5) or using no method of contraception (31.8).

There are statistically significant differences in contraceptive method used by race/ethnicity (Table 11b). About 31.1% of Non–Hispanic white women used a progestin-only method; they used non-hormonal methods or no contraception less often (29.0% and 25.6% respectively). In contrast, a higher percent of non-Hispanic black mothers (41.4%) used a progestin-only method. Very few used a non-hormonal method, (18.8%) but 27.1% of non-Hispanic black mothers did not use birth control during this period of time. Hispanic mothers were most likely to use non-hormonal methods (37.0%), and least likely to go without contraception (19.8%). All race/ethnic groups had low rates of usage for combined estrogen/progestin methods.

Differences were found between women of different educational attainment as well (Table 11b). Women with less than a high school education were mostly likely to use a non-hormonal method of contraception in the postpartum period (36.9%), women with a high school degree were most likely to use a progestin-only method (34.2%), while women with college or graduate degrees had similar usage rates for three categories: progestin-only, non-hormonal and no method.

Parity was strongly associated with the type of contraceptive used after birth (Table 11b). Nearly equal percentages of women with first-born and subsequent children did not to use contraception after birth (25.5% and 22.7% respectively). However, first time mothers were much more likely to use a hormonal method, 36.0% for progestin-only and 19.0% for combined estrogen/progestin, over a non-hormonal method (22.3%). In

contrast, 10.4% of multiparous women used a combined estrogen/progestin method, and their top choice was non-hormonal contraception (34.2%).

There was no statistically significant difference in contraceptive use among women based on the number of breastfeeding-supportive hospital practices they experienced, however, one of the individual practices included in this composite measure did show a significant difference; among those visited by an LC or other breastfeeding support person, more women chose progestin-only methods (32.3%) than non-hormonal (28.4%), no method (24.8%) or combined estrogen/progestin methods (14.4%) (Table 12). In contrast, among those who did not have an LC or other breastfeeding support person visit them, the most common form of contraception was a non-hormonal method (36.6%). Analyses of individual hospital practices showed no significant association between immediate skin-to-skin contact, rooming-in, observation of a feeding by an LC or other breastfeeding support person, or facility staff supporting the mother's infant feeding choice and type of contraceptive used after birth.

The other factors in the model, pregnancy wantedness, baby's gender, infant NICU stay, intention to breastfeed, timing of breastfeeding initiation, receipt of a formula sample bag, and the number of breastfeeding-related hospital practices experienced by the mother, were not significantly associated with type of postpartum contraceptive used. The variable for region of birth was not significant in any model and a likelihood ratio test was used to determine that it should be dropped from the final model.

Although pregnancy wantedness was not significantly associated with contraceptive use, trends in our data suggest that it might be a worthwhile topic for further exploration (Table 11b). Women who reported that their pregnancy was

139

unwanted or mistimed were less likely to not use contraception after birth (19.4%) than women with timely/wanted pregnancies (25.7%), while women who viewed all pregnancies as wanted were the most likely to use no form of birth control after birth (28.3%). When they did use contraception, these women most often used non-hormonal methods (31.8%), and women with wanted, timely pregnancies used non-hormonal and progestin-only methods about equally (29.5% and 31.4%). In contrast, those with unwanted or mistimed pregnancies used progestin-only contraception more often than any other type (36.7%).

Multivariate Analysis of the Predictors of Postpartum Contraceptive Use

Using log binomial regression models of pairs of contraceptive methods, maternal age ($p<0.0001$), breastfeeding duration ($p<0.0001$), race/ethnicity ($p<0.01$), maternal educational attainment ($p<0.05$), having a first-born child ($p<0.0001$), and visit by a lactation consultant or other breastfeeding support person ($p<0.05$) were associated with type of contraceptive used in the postpartum time period in at least one of the pair-wise comparisons (Table 13). The wantedness of the pregnancy, the baby's gender, infant NICU stay, an interaction between infant NICU stay and infant first-born status, breastfeeding intention, timing of breastfeeding initiation, receipt of a formula sample bag, and an interaction between maternal age and the number of hospital practices experienced by the mother were not associated with the type of contraception used after birth.

In the comparison of those who used progestin-only methods versus no form of contraception, only maternal age was significantly associated with postpartum

contraceptive use (RR 0.95, 95% CI 0.98-0.99) (Table 13). Each year of maternal age was associated with a 5% increased risk of using progestin-only method in the postpartum time-frame compared to using no method of contraception ($p<0.05$). Similarly, in the comparison of those who used progestin-only methods versus non-hormonal methods, there was a 6% increased risk per year of maternal age for using progestin-only methods compared to use of non-hormonal methods (RR 0.94, 95% CI 0.90-0.98).

Other factors significantly associated with contraceptive use in this regression model were race/ethnicity, education, NICU stay, and hospital practices (Table 13). Blacks were at higher risk of using progestin-only methods compared to non-hormonal methods than whites (RR 1.28, 95% CI 1.08-1.51), Hispanics (RR 1.29, 95% CI 1.03-1.61), and 41% higher risk than those classified as other (RR other vs. black 0.59, 95% CI 0.36-0.98). Compared to women who had less than a high school degree, mothers with a college degree had a 42% higher risk of using progestin-only contraception after birth (RR 1.42, 95% CI 1.09-1.86), and women with a graduate degree had 47% higher risk (RR 1.47, 95% CI 1.08-2.01). Having an infant admitted to the NICU was associated with use of progestin-only contraception (RR 1.40, 95% CI 1.08-1.81), as were breastfeeding-related hospital practices (RR 1.08, 95% CI 1.00-1.16).

None of the factors explored in this analysis was significantly associated with the use of combined estrogen/progestin contraceptive methods over either no method or progestin-only methods (Table 13). However, in the model comparing use of combined estrogen/progestin methods to non-hormonal methods, race/ethnicity and having a first-born child (RR 1.46, 95% CI 1.09-1.96) was associated with contraceptive use.

Compared to Hispanics, non-Hispanic blacks were at 74% higher risk (RR 1.74, 95% CI 1.04-2.92) and non-Hispanic whites were at 35% higher risk (RR for Hispanic vs. white 0.65, 95% CI 0.43-1.00) of using a combined method of birth control.

DISCUSSION

In this analysis, significant predictors of the type of contraceptive used include maternal age, maternal educational attainment, race/ethnicity, first birth, infant NICU stay, and the number of breastfeeding-related hospital practices experienced by the mother. More factors were found to be associated with use of progestin-only methods than combined estrogen/progestin methods in this analysis, which may be due in part to the lower prevalence of combined hormonal methods in this population (13.5%). This lower prevalence is not surprising since their use is generally contra-indicated for breastfeeding women according to the CDC.

The comparison group used in the pair-wise regressions had an impact on the results of the log binomial regressions. Significant results were found for both types of hormonal contraception, combined estrogen/progestin and progestin-only, in comparison with users of non-hormonal methods. However, for models of combined estrogen/progestin methods, neither of the other comparison groups produced significant results. For progestin-only methods, only maternal age was significant when comparing with those who used no form of contraception, and this did not improve on the results

using the non-hormonal group for comparison since maternal age was also found to be significantly associated in that model. This suggests that the control group used in studies of postpartum contraception may impact the ability of these studies to detect differences in patterns of use. Much of the literature used by the WHO and CDC to evaluate postpartum contraception, however, has as a control group those who are not using contraception. Many of these studies report no effect of hormonal methods, particularly progestin-only methods, but the results of this study suggest that this could be due to use of an ineffective control group. Women who do not use contraception after birth may represent a very different population that those who use contraception in this period. For instance, partnership status could be correlated with contraceptive use since women without partners may not be sexually active. Thus, studies that use those who do not use contraception as the comparison group may not be adequately controlling for partnership status, which has been shown to be positively associated with breastfeeding outcomes. (156,158,160)

In comparisons between progestin-only use and non-hormonal or no method of contraception, maternal age was associated with a 4.7% and 6.2% lower risk, respectively, of using a progestin-only method. That is to say that for each year older, mothers were about 5%-6% less likely to use a progestin-only method compared to the other two categories. Results for combined hormonal methods also showed a protective trend of age against use of hormonal contraception, but were not significant. This difference across ages may reflect women returning to methods they used before pregnancy since younger women tend to use hormonal contraception in higher proportions than older women. It could also be related to a decline in sexual activity with

age, which may be associated with not using contraception. Older mothers in our model are also more likely to not be using contraception, indicating that pregnancy prevention may play a smaller role in their decision making than for younger mothers. Healthcare providers may also play a role in this difference, suggesting or encouraging hormonal methods more often for younger mothers. Clinicians may assume or younger mothers may indicate that preventing future pregnancies is more important to them than older women, leading care providers to suggest different methods in an attempt to give these women reliable control over their fertility.   Estrogenic hormonal contraception is contra-indicated with age, which could mean that older mothers are avoiding hormonal methods as the risk of side-effects increases. In addition, younger women were traditionally steered away from highly effective non-hormonal methods like copper IUDs for fear of complication-induced sterility. Differences in contraceptive use after birth follow similar patterns to breastfeeding duration, which is shorter for younger mothers. This highlights a need to understand the association between the type of contraceptive used while breastfeeding and breastfeeding outcomes to ensure that contraceptive use is not contributing to this health disparity.

Race/ethnicity and parity were the only two factors that were associated with the use of combined estrogen/progestin methods after birth. Race/ethnicity was also a strong predictor of progestin-only use. Black women had a higher risk of using a progestin-only method compared to a non-hormonal method when compared with both white and Hispanic mothers, and had a 74% higher risk than Hispanic mothers of using a combined estrogen/progestin method over non-hormonal contraception (p<0.05), with a similar non-significant trend compared to white mothers. So, black mothers are using hormonal

contraception more than other racial and ethnic groups and they also have the lowest breastfeeding rates. (160,164,165) If clinical reports suggesting that hormonal contraception negatively impacts breastfeeding outcomes are true, this suggests that the contraceptive use patterns of black mothers may contribute to the health disparity in breastfeeding outcomes for black mother-baby dyads. Contraceptive use patterns of

Hispanic mothers would be consistent with this possibility. Hispanic mothers have the highest rate of breastfeeding, and although they are the group with the highest use of postpartum contraception, with over 80% using birth control, they use non-hormonal methods (37.0%) much more often than white (29.0%) or black (18.8%) mothers. Similarly, women classified as other also had high breastfeeding rates and used non-hormonal contraception more often than any other form (40.5%).

There are clear racial and ethnic differences in contraceptive use. Black mothers use progestin-only methods much more often than whites or Hispanics, and have the highest use of hormonal methods of any type. Hispanic mothers are the most likely to use contraception, and tend to favor non-hormonal methods, whereas white women are about evenly split between non-hormonal, progestin-only and no use, but are the group most likely to use combined hormonal contraception. While sometimes thought to represent differences in health factors, race and ethnicity in this case is most likely a proxy for social factors that influence a woman's healthcare choices, as well as those offered to her by her healthcare provider or available to her through her health insurance. These factors would likely need to be considered for racial/ethnic patterns of use to be changed.

Less educated mothers were more likely to use contraception after birth than more educated women, suggesting that pregnancy prevention is more important for less educated mothers perhaps reflecting differences in socio-economic status and the perceived impact of a subsequent pregnancy on their household. Our findings suggest that identifying and promoting effective birth control that is compatible with breastfeeding is an important factor in improving the disparity in breastfeeding continuation between more and less educated mothers.

Women with college and graduate degrees were at higher risk of using a progestin-only method over a non-hormonal method when compared to women with less than a high school education. This may indicated that more educated mothers are more likely to follow the CDC recommendations than less educated mothers. However for combined hormonal methods, this trend shifts; mothers with the lowest educational attainment, less than high school, and mothers with the highest, graduate degrees, are both more likely to avoid combined hormonal methods than women in the middle of the educational spectrum, high school and college graduates. If we assume education is a proxy for having more resources, then access to healthcare and the cost of a contraceptive method may be a more significant factor in contraceptive choice for less educated mothers compared to women in the middle of the educational spectrum. Additionally, higher education may result in the women being more informed about which methods are contraindicated during breastfeeding.

Pregnancy wantedness was not significantly associated with the type of contraceptive used after birth; however, trends in our data suggest that this topic might merit future research. The higher rates of contraceptive use among those who reported

this was an unwanted or mistimed pregnancy suggest that wantedness of the pregnancy

may be a factor in choosing contraception after birth, and that a woman's attitude about

her pregnancy may affect her preference for birth control in the postpartum period. This

study may underestimate the effect of pregnancy wantedness on contraceptive use after

birth if the women in this study were more successful in controlling their fertility then the

general population, or demonstrated bias in their response to the survey question in favor

of a more positive perspective, especially an issue since the women are asked

retrospectively after the baby's birth. Over 60% of women reported that their pregnancy

was timely and wanted, and only eight women reported that their pregnancy was

unwanted. In comparison, national data suggest that about half of all pregnancies in the

US are unplanned. Pregnancy intention has been shown to be associated with

breastfeeding outcomes. (182) Pregnancy wantedness may follow similar trends, an idea

supported by the association between pregnancy wantedness and other infant care

outcomes like antenatal care, stunting and later mental health for the child (179-181).

First-time motherhood is the second, and only other, characteristic that predicts

use of combined estrogen/progestin contraception in this population. First-time mothers

were at 46% higher risk of using a combined hormonal method compared to non-

hormonal methods, with similar non-significant trends with the other comparison groups.

The same issues that applied to the higher use of progestin-only methods by younger

mothers would be a factor here as well. However, the impact of combined hormonal

methods on breastfeeding is thought to be more profound than for progestin-only

methods and therefore the consequences for breastfeeding of this choice may be more

pronounced. The higher risk of using combined hormonal methods among first-time

mothers suggests that these women need better information about and promotion of types of contraception that are compatible with breastfeeding. Additional time might be needed in prenatal and postpartum obstetric appointments where contraception is discussed in order to provide more thorough counseling on contraceptive options to primiparous mothers.

Mothers whose babies have been in the NICU are at significantly higher risk of using a progestin-only method over non-hormonal contraception (38.9%, p<0.05). These women may perceive a greater need for birth control because of the separation from their child or because they are not able to fully breastfeed their baby. Changes in the standard of care at many NICUs now often encourage mothers to breastfeed, so these mothers may also receive more education about breastfeeding-friendly contraception, and be made more aware of the CDC recommendations for contraceptive use while breastfeeding. This is supported by the finding that the number of breastfeeding-related maternity practices experienced by the mother were also associated with the type of contraceptive used, with a 7.6% increased risk of using a progestin-only method compared to non-hormonal methods with each additional practice reported by the mother. Likewise, examination of the individual practices that comprised the 'Hospital Practices' variable, revealed a significant association between a visit by an LC or breastfeeding support person and the type of contraceptive used (Table 2). It could be that women experiencing breastfeeding difficulties are both more likely to receive a breastfeeding support visit and more likely to contracept, but since non-hormonal methods are considered by breastfeeding advocates to be the more conservative choice for breastfeeding preservation, these results, like the findings for hospital practices in general are

surprising. However, given that the CDC recommendations do not prioritize non-hormonal methods over progestin-only methods while breastfeeding, these results may indicate that women are being effectively educated about the current guidelines before initiating contraceptive use and that they are following those guidelines. Many women seem to be prioritizing pregnancy prevention over preservation of breastfeeding, either via a conscious decision or from lack of awareness about the trade-offs. This further underscores the importance of gathering accurate information about the association between exposure to progestins while breastfeeding and the need to translate this work into evidence based guidelines for contraceptive use during lactation. Women who had not intended to breastfeed before birth, but did initiate breastfeeding, were the most likely sub-population to use combined estrogen/progestin methods (22.6%). However, only 2.4% of mothers in this sample fell into this category. The higher use of contraceptive methods that are not recommended during breastfeeding could represent a lack of commitment to breastfeeding by these women, or it could be explained by ignorance of breastfeeding-related issues among women who did not think these topics were relevant to them prior to birth. Since these women are a breastfeeding success story, further attention should be paid to whether their use of contraceptive methods that are contraindicated for breastfeeding represents an intentional choice on their part or ignorance of potential contraindications. Policy, therefore, might include targeted continued postpartum counseling on both breastfeeding and contraception for this population.

LIMITATIONS

This sample population, selected from North Carolina Birth Certificates, was contacted by landline telephone. Differences in the covariates and in contraceptive use may exist between women who could be reached on a landline telephone and those who could not. For instance, people who use cell phones exclusively would not be reached, and this could disproportionately exclude younger, poorer, and more transient mothers from the sample leading to sample bias. If willingness to participate in a telephone survey were not randomly distributed, the sample would also be biased. These concerns are partially addressed in two ways. First, the random selection process using birth certificate records provides an unbiased foundation for sample selection. In addition, many measures were undertaken to contact potential subjects including multiple contact attempts, contact at different times of the day and week, and contact attempts over several months. Furthermore, if the potential participant declined, efforts were made by specially trained personnel to convince the potential study subjects to participate.

The retrospective study design relied on maternal self-report and is vulnerable to recall bias which would be more likely to affect transient factors and factors with perceived positive or negative connotation. For example, unwanted and mistimed pregnancies are reported less often in this sample than has been found in national data. Mothers may be reluctant to tell the interviewer that their pregnancy was unwanted or mistimed, and she might also unconsciously re-evaluate the wantedness of her pregnancy as she begins to bond with her baby. Similarly, a mother's recall of her intention to breastfeed may change in light of her actual experience of breastfeeding. Reporting of

hospital practices may be also be bias by events that happen later, and mothers could simply not remember what occurred during that time. Some may not even know whether and when events happened, which could be correlated with maternal or infant health. Finally, reporting of contraceptive use may be subject to recall bias, especially if more than one method has been used since birth. This sample is likely comparable to other studies in the field of breastfeeding research since results from this study are consistent with other breastfeeding studies on covariates commonly reported in the literature.

Non-random missing data could also lead to sample bias, however the amount of missing data for the variables used in the model was 1%-3%, which is very low. There may be additional factors associated with contraceptive use not captured in this model. For instance, partnership status, whether the mother is sexually active, and whether she has achieved her desired family size could all be important factors in using contraception, but were not available in the dataset.

Timing of contraceptive use would also have been useful to provide a more complete description of postpartum contraception. This is particularly true for women who reported using more than one method since birth because the timing, order and duration of these methods were unknown. Nonetheless, this sample is unusual in that is has information about breastfeeding outcomes as well as information about contraceptive use, enabling analysis of contraception use during breastfeeding. Few analyses of postpartum contraceptive use have been carried out in adult populations, as opposed to among adolescent mothers. So this study also contributes to the literature by describing factors associated with contraceptive use in this large demographic.

CONCLUSION

Postpartum contraceptive use by women who initiated breastfeeding is associated with maternal age, maternal educational attainment, race/ethnicity, first birth, infant NICU stay, and the number of breastfeeding-related hospital practices experienced by the mother. Differing contraceptive use corresponds with varying breastfeeding rates, suggesting that the issues may be related either with common etiology or by direct effects between them. Pregnancy prevention may outweigh breastfeeding protection in a clinician's advice and in maternal choice of contraception after birth. If so, accurate and available information about the impact of hormonal contraception on breastfeeding is need by these women, as well as having access to reliable and attractive contraceptive methods which are compatible with breastfeeding.

Table 9: Characteristics of the Population From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11. (N=1,319).

	Total	Percentage of Total
	N=1,319	100%
Maternal Age (years)		
Mean	30.3	
Median	31	
Race/Ethnicity		
Non-Hispanic White	876	66.4%
Non-Hispanic Black	133	10.1%
Hispanic	273	20.7%
Other	37	2.8%

Maternal Education		
Less than High School	157	11.9%
High School	345	26.2%
College	536	40.6%
Graduate School	281	21.3%
Pregnancy Wantedness		
Wanted at This Time	816	61.9%
Not Wanted / Mistimed	330	25.0%
All Pregnancies Wanted	173	13.1%
First Child		
Yes	475	36.0%
No	844	64.0%
Baby's Gender		
Female	684	51.9%
Male	635	48.1%
NICU Stay		
no	1,171	88.8%
yes	148	11.2%
Intention to Breastfeed		
No	31	2.4%
Yes	1,288	97.6%
Timing of Initiation		
< 1 Hour	584	44.3%
1-2 Hours	265	20.1%
2-24 Hours	336	25.5%
> 24 Hours	134	10.1%
Received Formula Sample Bag		
No	311	23.6%
Yes	1,008	76.4%

Hospital Practices			
Mean	3.9	3.9
Median	4	4

Table 10: Percentage of the Sample at Each Month Who are Still Breastfeeding, Among Women Who Initiated Breastfeeding (N=1,319). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11.

	Not Breastfeeding n (%)	Breastfeeding n (%)
1 Month	169 (12.8%)	1,150 (87.2%)
2 Months	336 (25.5%)	983 (74.5%)
3 Months	589 (44.7%)	730 (55.3%)
4 months	1,017 (77.1%)	302 (22.9%)
5 Months	1,298 (98.4%)	21 (1.6%)
> =6 Months	1,310 (99.3%)	9 (0.7%)

Table 11a: Characteristics of the Population (continuous variables) by Method of Postpartum Contraceptive Use (N=1,319). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11, and Limited to Women Who Initiated Breastfeeding.

	No Method n (%)	Non-Hormonal n (%)	Progestin-Only n (%)	Combined Estrogen / Progestin n (%)	Total n (%)
Total	323 (24.5%)	395 (29.9%)	423 (32.1%)	178 (13.5%)	1,319 (100%)
Maternal Age*** (years)					
Mean	31.8	31.5	28.9	28.5	30.3
Median	32	32	30	29	31
Infant Age at interview (months)					
Mean	3.28	3.23	3.26	3.49	3.29
Median	3	3	3	3	3
Hospital Practices					

	Mean	3.9	3.8	3.9	4.0	3.9
	Median	4	4	4	4	4

*** p<0.001   ** p<0.01   * p<0.05

	No Method n (%)	Non-Hormonal n (%)	Progestin-Only n (%)	Combined Estrogen / Progestin n (%)	Total n
	323 (24.5%)	395 (29.9%)	423(32.1%)	178(13.5%)	1,319
Race/Ethnicity**					
Non-Hispanic White	224 (25.6%)	254 (29.0%)	272 (31.1%)	126 (14.4%)	876
Non-Hispanic Black	36 (27.1%)	25 (18.8%)	55 (41.4%)	17 (12.8%)	133
Hispanic	54 (19.8%)	101 (37.0%)	87 (31.9%)	31 (11.4%)	273
Other	9 (24.3%)	15 (40.5%)	9 (24.3%)	4 (10.8%)	37
Maternal Education*					
Less than High School	28 (17.8%)	58 (36.9%)	52 (33.1%)	19 (12.1%)	157
High School	70 (20.3%)	101 (29.3%)	118 (34.2%)	56 (16.2%)	345
College	146 (27.2%)	148 (27.6%)	167 (31.2%)	75 (14.0%)	536
Graduate School	79 (28.1%)	88 (31.3%)	86 (30.6%)	28 (10.0%)	281
Pregnancy Wantedness					
Wanted at This Time	210 (25.7%)	241 (29.5%)	256 (31.4%)	109 (13.4%)	816
Not Wanted / Mistimed	64 (19.4%)	99 (30.0%)	121 (36.7%)	46 (13.9%)	330

Table 11b: Characteristics of the Population by Method of Postpartum Contraceptive Use (N=1,319). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11, and Limited to Women Who Initiated Breastfeeding.

All Pregnancies Wanted	49 (28.3%)	55 (31.8%)	46 (26.6%)	23 (13.3%)	173
First Child*					
Yes	108 (22.7%)	106 (22.3%)	171 (36.0%)	90 (19.0%)	475
No	215 (25.5%)	289 (34.2%)	252 (29.9%)	88 (10.4%)	844
Baby's Gender					
Female	171 (25.0%)	202 (29.5%)	230 (33.6%)	81 (11.8%)	684
Male	152 (23.9%)	193 (30.4%)	193 (30.4%)	97 (15.3%)	635
NICU Stay					
no	290 (24.8%)	357 (30.5%)	367 (31.3%)	157 (13.4%)	1,171
yes	33 (22.3%)	38 (25.7%)	56 (37.8%)	21 (14.2%)	148
Intention to Breastfeed					
No	8 (25.8%)	5 (16.1%)	11 (35.5%)	7 (22.6%)	31
Yes	315 (24.5%)	390 (30.3%)	412 (32.0%)	171 (13.3%)	1,288
Timing of Initiation					
< 1 Hour	162 (27.7)	172 (29.5%)	184 (31.5%)	66 (11.3%)	584
1 to <2 Hours	53 (20.0%)	84 (31.7%)	88 (33.2%)	40 (15.1%)	265
2 to 24 Hours	77 (22.9%)	94 (28.0%)	110 (32.7%)	55 (16.4%)	336
> 24 Hours	31 (23.1%)	45 (33.6%)	41 (30.6%)	17 (12.7%)	134
Received Formula Sample Bag					

No	83 (26.7%)	87 (28.0%)	108 (34.7%)	33 (10.6%)	311
Yes	240 (23.8%)	308 (30.6%)	315 (31.3%)	145 (14.4%)	1,008

*** p<0.001 ** p<0.01 * p<0.05

Table 12: Association of Lactation Support Visit in Hospital with Contraceptive Method Use (N=1,319). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11, and Limited to Women Who Initiated Breastfeeding.

	No Method n (%)	Non-Hormonal n (%)	Progestin-only n (%)	Combined Estrogen / Progestin n (%)	Total n (%)
Visit*†					
No	56 (23.1%)	89(36.6%)	75(30.9%)	23(9.5%)	243 (18.4%)
Yes	267(24.8%)	306(28.4%)	348(32.3%)	155(14.4%)	1,076 (81.6%)
Total	323	395	423	178	1,319 (100%)

* p<0.05
† This variable is included in the ordinal "Hospital Practices" variable and is not included as a separate variable in the analyses.

Table 13: Risk Ratios From Log Binomial Regressions of Pairs of Contraceptive Types Used in the Postpartum Period by Women Who Initiated Breastfeeding (N=1,319). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11

	Progestin-only vs. No Method RR (95% CI)	Progestin-only vs. Non-Hormonal Methods RR (95% CI)	Combined Estrogen / Progestin Methods vs. No Method RR (95% CI)	Combined Estrogen / Progestin vs. Non-Hormonal Methods RR (95% CI)	Combined Estrogen / Progestin vs. Progestin-only RR (95% CI)
Maternal Age	0.95* (0.92, 0.99)	0.94* (0.90, 0.98)	0.98 (0.91, 1.06)	1.00 (0.91, 1.09)	1.08 (0.98, 1.18)
Race/Ethnicity					
White	Referent				
Black	0.96 (0.79, 1.16)	1.28** (1.08, 1.51)	0.73 (0.48, 1.12)	1.14 (0.78, 1.67)	0.74 (0.48, 1.15)
Hispanic	1.08 (0.90, 1.30)	0.99 (0.81, 1.23)	0.86 (0.60, 1.24)	0.65* (0.43, 1.00)	0.83 (0.56, 1.22)
Other	0.90 (0.58, 1.39)	0.76 (0.47, 1.24)	0.87 (0.41, 1.83)	0.67 (0.31, 1.45)	0.91 (0.39, 2.17)
Maternal Education					
Less than High School	Referent				

High School	1.10 (0.89, 1.35)	1.21 (0.96, 1.52)	1.14 (0.71, 1.82)	1.16 (0.70, 1.91)	1.12 (0.71, 1.8)
College	1.18 (0.91, 1.52)	**1.42*** (1.09, 1.86)	1.13 (0.65, 1.94)	1.16 (0.67, 2.01)	1.05 (0.60, 1.8)
Graduate School	1.21 (0.90, 1.64)	**1.47*** (1.08, 2.01)	0.98 (0.52, 1.86)	0.938 (0.49, 1.81)	0.76 (0.39, 1.5)
Pregnancy Wantedness					
Wanted at this Time	Referent				
Not Wanted / Mistimed	1.03 (0.89, 1.19)	0.97 (0.83, 1.14)	0.92 (0.69, 1.24)	0.85 (0.63, 1.14)	0.86 (0.63, 1.18)
All Pregnancies Wanted	0.89 (0.71, 1.12)	0.91 (0.72, 1.15)	0.85 (0.60, 1.20)	0.81 (0.57, 1.15)	0.99 (0.68, 1.44)
First Born	0.98 (0.85, 1.14)	1.07 (0.91, 1.25)	1.20 (0.92, 1.56)	**1.46*** (1.09, 1.96)	1.32 (0.98, 1.78)
Baby's Gender	1.03 (0.91, 1.17)	1.07 (0.94, 1.22)	0.89 (0.71, 1.13)	0.87 (0.68, 1.10)	0.80 (0.63, 1.03)
NICU Stay	1.14 (0.89, 1.46)	**1.40*** (1.08, 1.81)	0.84 (0.46, 1.52)	1.13 (0.63, 2.00)	0.75 (0.40, 1.39)
NICU Stay x First Born	1.04 (0.74, 1.45)	0.80 (0.56, 1.13)	1.54 (0.78, 3.04)	0.99 (0.499, 1.95)	1.23 (0.57, 2.67)

Intended to Breastfeed	1.10 (0.75, 1.60)	0.85 (0.62, 1.17)	0.68 (0.38, 1.19)	0.46* (0.27, 0.78)	0.71 (0.38, 1.32)
Timing of Initiation					
<1 Hour	Referent				
1 to <2 Hours	1.15 (0.98, 1.36)	1.01 (0.85, 1.21)	1.35 (1.00, 1.84)	1.17 (0.85, 1.61)	1.17 (0.84, 1.62)
2 to 24 Hours	1.04 (0.89, 1.22)	1.020 (0.86, 1.20)	1.26 (0.93, 1.71)	1.27 (0.94, 1.70)	1.25 (0.91, 1.72)
> 24 Hours	0.95 (0.74, 1.21)	0.88 (0.67, 1.14)	1.20 (0.73, 1.97)	1.06 (0.64, 1.75)	1.16 (0.68, 1.96)
Received Formula Sample Bag	0.99 (0.86, 1.14)	0.95 (0.82, 1.10)	1.28 (0.95, 1.71)	1.24 (0.92, 1.67)	1.38 (1.00, 1.90)
Hospital Practices	0.99 (0.93, 1.06)	**1.08*** (1.00, 1.16)	1.02 (0.90, 1.15)	1.13 (0.99, 1.28)	1.05 (0.92, 1.21)
Hospital Practices X Maternal Age	1.00 (0.99, 1.01)	1.01 (1.00, 1.02)	0.99 (0.98, 1.01)	0.99 (0.97, 1.01)	0.98 (0.96, 1.01)
** p<0.01 * p<0.05					

CHAPTER IV: EFFECT OF PROGESTIN-ONLY CONTRACEPTIVE USE ON BREASTFEEDING DURATION

INTRODUCTION

Breastfeeding and family planning are both important public health issues with personal and societal implications. In the postpartum period, these issues come together in a way that is crucial to understand if lasting headway is to be made on both of these public health priorities.

Breastfeeding is associated with better short and long-term health outcomes for both mother and baby. Breastfed infants have lower rates of a wide range of illnesses including ear infections, bacterial meningitis, urinary tract infections, intestinal infections, diarrhea, and childhood cancers. (7-15) Lower rates of sudden infant death syndrome, asthma, obesity, and diabetes are also seen in children who are breastfed. (16-24) Cognitive development may also be enhanced by breastfeeding. (25-27)

Mothers also experience better immediate and long-term health outcomes with breastfeeding. Women who breastfeed experience less postpartum blood loss and more rapid uterine involution. (28) In the long-term, women who breastfeed have lower rates of breast and ovarian cancer, fewer hip fractures and less osteoporosis later in life. (29-33)

These differences in health outcomes translate into a substantial health and financial. (34) The cost of infant morbidity and mortality that could be prevented by meeting the AAP guideline of exclusive breastfeeding until 6 months is estimated to cost the United States (US) $13 billion each year. (35)

Improving breastfeeding outcomes has been a key goal in the Healthy People initiatives. The 2020 goals call for an 81.9% initiation rate, 60.6% continuation at six months, and 25.5% exclusive breastfeeding at six months. (6) However, in assessing the success of the Healthy People 2010 initiative, it was found that in 2010 while 76.9% of infants had ever been breastfed and 47.2% of women were still nursing at six months, only 16.3% were breastfeeding exclusively at six months. This falls short of universal adherence to the current recommendation of 6 months exclusive breastfeeding of the World Health Organization (WHO) and of the AAP. (5)

So, while some success has been achieved in improving breastfeeding initiation rates, much work still remains to be done on rates of continuation and exclusivity. Understanding the factors that affect breastfeeding continuation, therefore, is important to meeting national and international breastfeeding goals, and for improving maternal and infant health in the US.

One key area of controversy is how contraceptive use and breastfeeding might interact in the postpartum period. In particular, the compatibility of hormonal contraceptive methods with breastfeeding is widely disputed. Clinical reports from lactation specialists suggest that these methods reduce milk supply and lead to weaning, whereas evaluation of the available literature by the Centers for Disease Control (CDC) led to formal recommendations in 2008 and 2009 and updated in 2013 that progestin-only

164

methods of birth control were compatible with breastfeeding, some even in the first hours after birth. (99,100,102) Further complicating the issue is the fact that the WHO espouses different recommendations based on the same body of scientific literature, warning against progestin-only methods in the early weeks of breastfeeding. (98)

What is not disputed is the importance of family planning for women, their children, and society. The world community set as a goal "universal access to reproductive health," including family planning at the International Conference on Population and Development (ICPD) in Cairo, citing, in particular, the fact that family planning is one of the most cost effective ways to combat poverty. Still, researchers supported by the Bill and Melinda Gates Foundation estimated that, as of 2009, more than 200 million women around the world lacked access to modern methods of contraception, and furthermore they predicted that by 2050 this would increase by 40%. (36,37)

In the US alone, unintended pregnancy is estimated to cost $4.5 billion each year. (41) The burden of unplanned pregnancies falls disproportionately on ethnic and racial minorities and those with less education, the same groups that tend to have lower financial means and access to healthcare. Between 1994 and 2001, the rate of unintended pregnancy among white women was estimated to be 35 per 1,000, while black women had 98 per 1,000 and Hispanic women had 78 per 1,000. (39) Education is also strongly associated with unintentional pregnancy, with 26 per 1,000 for women with college degrees, and 76 per 1,000 for women without a high school degree. Contraceptive use follows similar racial and education patterns and is thought to be both a response to and a cause of these differences. (40)

A significant portion of this issue is postpartum contraception. It is estimated that 100 million women around the world make decisions about contraception after childbirth each year. (42) The public health implications of postpartum family planning are particularly important since inter-birth interval has serious implications for both maternal and infant health. Women with birth intervals of less than six months are at increased risk for maternal mortality (OR 2.54; 95% CI 1.22-5.38), third-trimester bleeding (OR1.73; 95% CI 142-2.24), premature rupture of membranes (OR1.72; 95% CI 1.53-1.93), puerperal endometritis (OR1.33; 1.22-1.45), and anemia (OR1.30; 95% CI 1.18-1.43). (43) Among women with previous Cesarean deliveries, birth intervals of less than 18 months were associated with a higher risk of uterine rupture, 2.25% vs. 1.05% for intervals of 19 months or longer, doubling the risk of this rare event. (44) Thus, pregnancy prevention is an important health issue for postpartum women.

While the Lactational Amenorrhea Method (LAM) has been shown to be effective for women who are breastfeeding, many women may not be meeting the requirements or simply prefer to use contraception after birth. (45-47) The biological pathways that establish and maintain lactation are responsive to endogenous estrogen and progesterone. Moreover, exogenous estrogens are reported to reduce milk supply and progestins are suspected to as well. Accurate information about the compatibility of specific contraceptive methods with breastfeeding is needed for these women to make informed choices about both. The current debate over the impact of progestin-only methods on breastfeeding has far-reaching implications for women and society, and deserves attention.

This study aims to increase understanding of the association between progestin-only methods of birth control and breastfeeding outcomes in the early months of life. Much of the research on which the WHO and CDC recommendations are based were carried out in countries like Egypt and Chile that have very different breastfeeding patterns than seen in the US. Moreover, a substantial portion of this literature is over 20 years old, raising the question of whether the contraceptive methods available at that time and the social context, for instance women's roles, attitudes towards breastfeeding, and awareness of the health implications of breastfeeding, are generalizable to the US today. The survey used for this analysis, collected in 2010-11 in North Carolina, provides data to addresses a number of these issues. North Carolina falls in the middle of the spectrum of US states in terms of breastfeeding initiation and continuation, has a variety of urban and rural areas, and has immigration from other parts of the country and beyond, mixing social norms from other regions. Geophysically, socio-culturally and economically, there is a diversity of settings within the state that encompass a wide spectrum of the American social context. Politically, the electorate splits closely between major parties. There is a sizable minority of African Americans and Hispanics. Together, this makes North Carolina an informative setting to explore the current state of breastfeeding in the US, and well suited to addresses the question of whether progestin-only forms of contraception are associated with shorter durations of breastfeeding.

MATERIALS AND METHODS

Subjects

A sample of North Carolina mothers was drawn from birth certificate data from April 2010 to March 2011 to assess response to a Purple Crying campaign. Additional questions were added for this study. Of the approximately 130,000 births in the state annually, about 2,000 mothers with infants targeted to be between the ages of two and three months were selected. Address and name information from the birth certificate were used to back-match landline telephone numbers for these women, and only those with working, in-state telephones were considered eligible for study participation. A one-time telephone survey was administered in English or Spanish to the female parent or legal guardian. If more than one child in the household met study criterion, the child on the birth certificate was referenced for the study. Otherwise, the identity of the parent and child were not verified to match the birth certificate data. This resulted in 1,669 interviews, including 25 partial interviews. There was over-sampling for Hispanic maternal ethnicity, urban/rural location, hospital size for delivery, and infant age to ensure variation in the data on key characteristics.

For the purposes of this analysis, looking at the association between postpartum contraceptive use and breastfeeding duration, the analytic sample was limited to women who initiated breastfeeding (N=1,404) and who were using a progestin-only, non-hormonal, or no method of contraception (1,141).

STATISTICAL ANALYSES

Chi-square and Kruskal Wallis tests were performed to assess differences between women who used each type of contraceptive in the postpartum period. Women who were still breastfeeding at the time of the interview were right censored in our analysis, whereas those who had ceased to breastfeed prior to the interview had actual durations of breastfeeding.

A Kaplan-Meier survival analysis of breastfeeding duration was performed using the method described by Cole and Hernán that utilizes inverse probability weights based on propensity scores to adjust for differences between the users of different contraceptive types. (207) Propensity scores for type of contraceptive used in the postpartum time-frame were based on maternal and infant demographic variables (maternal age, maternal education, race/ethnicity, baby's gender), psychosocial factors (pregnancy 'wantedness,' intention to breastfeed), health factors (infant NICU stay, parity, and an interaction term for NICU stay and parity), and breastfeeding-related maternity care practices: timing of breastfeeding initiation, receipt of a formula sample bag at hospital discharge, an ordinal variable for the number of Hospital practices experienced by the mother, and an interaction term for maternal age and hospital practices. In order to more readily evaluate the results, the same covariates were used to create the propensity scores for each analysis.

The model was developed beginning from a full model that included all variables found in the literature to be associated with breastfeeding outcomes and which were available in the survey. To assess the best way to code variables where more than one

logical option existed, nested models were compared using likelihood ratio tests with a cut-off of p<0.05. Non-nested models were compared using Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC), and parameters that were neither statistically significant at the p<0.05 level nor crucial factors from the literature were removed from the model. Covariates that were predictive in any model were retained.

Comparison of the distribution of propensity scores for the treatment groups was used to assess whether this method adequately controlled for differences between the groups. Furthermore, an analysis of the area of common support, that is where there is overlap in the distribution of propensity scores between the treatment and control groups, was made by trimming the propensity scores for each group at 1% and 99% cut-offs and restricting the analysis to innermost points of the two groups. (218,219)

Progestin-only method users were compared to those who used either non-hormonal or no method of contraception. Statistical Analyses were performed using SAS software version 9.2.

MEASURES

Demographic characteristics. The survey included demographic data for both the mother and infant, including infant race/ethnicity, infant gender, maternal age, maternal educational attainment, family household income, and the county of birth.

Mothers were asked to identify the race of their infant, and allowed to choose as many categories as they felt applied. They were asked separately about the infant's Hispanic ethnicity. Any child identified as being Hispanic was classified as Hispanic for

the purposes of this study, regardless of any racial identification. Among non-Hispanics, infants with only one race reported on the survey were identified as that race. Among the remaining study subjects who were reported to be mixed-race, any infant identified as being "white" in a separate question about whether the parent considered the child white, was identified as "non-Hispanic white." Next, those who were reported to be mixed-race with one race being black were identified as "non-Hispanic black." All remaining study subjects were classified as, "other," which included Asian, Pacific Islander, Hawaiian, Alaskan native, and Native American, and anyone who identified her child as "other".

Region of birth was categorized using the State of North Carolina's classification of counties into Western/Mountain, Piedmont, and Eastern/Coastal. Classification was based on the county of birth reported by the mother. However, in no analysis was region of birth significant, and a likelihood ratio test was used to determine that this variable should be dropped from the final model.

The mother's age was recorded in whole years from responses to a single question in the interview. Various methods of modeling were explored including binned and continuous coding and addition of a quadratic term. The Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC) were used to determine that maternal age could be sufficiently coded using a continuous variable. Furthermore, the quadratic term was not significant in the model and was therefore excluded. For ease of interpretation, maternal age was mean-centered in the analysis.

Health factors. Information about parity and admission to the neonatal intensive care unit (NICU) were gathered through the interview. Mothers were asked whether the infant

in the study had any older biological siblings. First-born status was extrapolated from this. NICU stay for this infant was asked directly in the survey.

Psychosocial factors. The World Health Organization (WHO) classifies pregnancy intention into four categories: wanted at this time, wanted not at this time, not wanted, and all pregnancies are wanted. Mothers were asked to identify the 'wantedness' of their pregnancy using the WHO categories. A single category that included both unwanted and mistimed pregnancies was included in this analysis because of small cell-size for unwanted pregnancies.

Mothers were also asked about their pre-birth breastfeeding intention and intended duration. Breastfeeding intention was collected as a dichotomous yes/no response, and intended duration was recorded in weeks.

Hospital practices. The mother's maternity experiences were assessed by asking her to report which of seven maternity care related practices she had experienced. These practices were derived from the WHO/UNICEF Ten Steps to Successful breastfeeding. (198) Many hospitals in North Carolina have restricted the provision of formula sample bags, possibly without or prior to implementing the other practices. (210) Therefore, receipt of a formula sample bag was analyzed independently from the other practices. Timing of initiation was also analyzed on its own because it can only be discussed for the sub-population that initiates breastfeeding.

The remaining practices were explored both independently and as a group via an index variable, coded zero to five, for the number of breastfeeding-friendly hospital

172

practices received. The practices were not specific to the Ten Steps, but are aspects of specific steps. These practices are immediate skin-to-skin contact between mother and infant after birth (Step 4), rooming-in at least 22 of every 24 hours (Step 7), visit by a Lactation Consultant (LC) or breastfeeding support person (proxy for Step 5), observation of a feeding by an LC or breastfeeding support person (also Step 5), and all facility staff supporting the mother's decision on infant feeding (also Step 5).

Postpartum contraceptive use. Postpartum contraceptive use was assessed by asking the mother to identify all methods she had used since the baby's birth. Four categories of contraceptive use, differentiated based on their reported impact on breastfeeding, were used to categorize the 17 distinct types of contraception reported by women in the study. For those reporting more than one method, the method in the category most contra-indicated for breastfeeding was selected based on the following order: combined estrogen/progestin, progestin-only, non-hormonal, and no method of contraception.

Breastfeeding. Duration of breastfeeding was determined based on the baby's age at the time of the survey if the mother reported that she was still breastfeeding, and if not, duration was measured based on the reported age of breastfeeding cessation. The baby's age was calculated from the date of the interview and the baby's birth date reported during the interview, and was then converted into weeks by dividing the results by seven and rounding to the nearest whole week. Age at cessation was collected in whole weeks. About 70% of the respondents were still breastfeeding at the time of the interview, and

173

therefore their breastfeeding duration was right censored in our analysis because a final duration was not available.

Interaction terms. An exploratory analysis of interactions between variables was carried out in a separate analysis of direct associations between the independent variables and breastfeeding duration using a Cox proportional hazards model of breastfeeding cessation. Interactions between the variables for hospital practices and maternal age, timing of breastfeeding initiation, NICU stay, infant gender, and intention to breastfeed were tested. In addition, interaction terms for first-born status and NICU stay and for the wantedness dummy variables were explored, as well as breastfeeding intention and infant gender. An interaction between infant NICU stay and first-born status was found to be significant in some analyses, and was, therefore, kept in the model for all regressions. An interaction between the mother's age and a proxy for all hospital practices developed as an ordinal variable was significant and remained in the model. Interactions between the individual hospital practices and maternal age were also explored, and a likelihood ratio test was used to determine that the ordinal variable and ordinal variable-maternal age interaction term were the best for the model.

Missing Data. The data set had a very low level of missing data, between one and three percent for most variables, with the exception of family household income and intended breastfeeding duration. A likelihood ratio test was carried out to determine whether including household income in the model did not have a significant effect on the results. Forest plots were used to assess whether estimates of the other variables were affected by

174

including or excluding income, and in no case did the change in parameter estimate exceed the confidence interval for that variable. Therefore, income was dropped from the model

The large amount of missing data for intended breastfeeding duration was non-random and could possibly be correlated with the mother's knowledge about, interest in, and/or commitment to breastfeeding. Therefore, the dichotomous variable for intention to breastfeed was chosen for use in our model, and not to use the information on intended duration.

A complete case analysis, excluding participants with missing data on any variable in the model, was performed.

IRB. This study received IRB approval from the University of North Carolina, Chapel Hill.

RESULTS

Descriptive Analysis: Univariate and Bivariate Distribution

The mean maternal age of the population in this sample was 30.6 years old, with a minimum of 14 and a maximum of 46 (Table 14). The sample was 65.7% non-Hispanic white, 10.2% non-Hispanic black, 21.2% Hispanic, and 2.9% other. There were slightly more female infants than male, 52.8% versus 47.2% respectively, and 11.1% of infants spent time in the NICU compared to about 6.7% nationally. (211). First time mothers made up 66.3% of the population and 12.1% of women had less than a high school

175

degree. 25.3% had a high school education, 40.4% had a college degree, and 22.2% had a graduate degree. The mean infant age at the time of the interview was 3.26 months (Table 16a), and across the range of infant ages there was a distribution of breastfeeding status (Table 15). In this population, 37.1% of women used a progestin-only form of contraception after birth, compared to 34.6% use of a non-hormonal method, and 28.3% use of no contraception (Table 16a).

There were significant differences in contraceptive use by maternal age (p<0.001, Table 16a). Women using no method of contraception were slightly older, on average (mean age 31.8) than women using a non-hormonal method (mean age 31.5) and both groups were significantly older than women who used a progestin-only method (mean age 28.9). Race/ethnicity was also a significant predictor of contraceptive use (p<0.01, Table 16b). While non-Hispanic white mothers were about equally represented across the three categories of contraception, non-Hispanic blacks were more likely to use no method (31.0%) or a progestin-only method (47.4%) than a non-hormonal method (21.6%), while Hispanic mothers were more likely to use a non-hormonal method (41.7%) over a progestin-only method (36.0%) or no method (22.3%). Contraceptive type varied significantly with maternal educational attainment (p<0.05). Mothers with less than a high school education most often used a non-hormonal method (42.0%), those with a high school degree were most likely to use a progestin-only method (40.8%), and college-educated and graduate school educated women used the three types in about equal proportion. Mothers with their first biological child   were most likely to choose a non-hormonal method (38.2%) in contrast, multiparous women were least likely to

choose a non-hormonal method (27.7%) and most likely to choose a progestin-only method (44.4%).

No statistically significant differences were found in the type of contraceptive used, in relation to the wantedness of the pregnancy, the baby's gender, whether the infant had been in the NICU, the mother's intention to breastfeed, the timing of breastfeeding initiation, whether the mother received a formula sample bag at hospital discharge, or the number of breastfeeding-related maternity practices she had experienced. However, among the hospital practices included in the ordinal variable, there was a significant difference in contraceptive type used in association with a visit by an LC or other breastfeeding support person (Table 17); women who were visited were more likely to choose a progestin-only method (37.8%), and women who did not receive a visit were more likely to choose a non-hormonal method (40.5%).

Survival Analysis of Breastfeeding Duration by Postpartum Contraceptive Use

The use of a Cox proportional hazards model of breastfeeding duration, as a function of type of contraception used since the baby's birth, allowed control for differences between the users of different types of contraception through inverse probability weights based on propensity scores for type of contraception used.

The Cox proportional hazards model comparing progestin-only methods to no method of contraception included 746 subjects with 70.4% right censored. No significant difference was seen in breastfeeding duration between users of progestin-only methods and those who used no form of birth control (Table 18). No effect was seen in either the crude analysis or the model using propensity score weighted independent variables to

control for differences between the groups, although the survival curve was slightly different in the adjusted model (Figure 6, Appendix 11). A visual examination of histograms of the propensity score weights for each study group showed a high degree of over-lap in the scores indicating that the propensity score was able to substantially control for differences between the treatment and control group (Appendix 1). Moreover, an analysis of the area of common support using a 1% cut-off showed consistent results with the main analysis.

There were 818 women included in the Cox proportional hazards model of progestin-only use compared to use of a non-hormonal method of contraception, and 69.0% of them were right censored (Table 18). No difference in breastfeeding duration was found between these groups in either the crude or propensity score weighted analyses, however, the adjusted survival curves showed a trend towards differentiated effects with use of a progestin-only method being associated with longer duration of breastfeeding than use of non-hormonal methods (Figure 6, Appendix 11). Visual examination of the propensity score weighting using histograms showed good success in matching the treatment and control groups, and an analysis of the area of common support using a 1% cut-off gave substantially similar results to the unrestricted analysis (Appendix 1).

DISCUSSION

There was no statistically significant difference in breastfeeding duration for women who used progestin-only methods of contraception compared to those who used

non-hormonal methods or no contraception. Clinical reports suggest that early postpartum use of progestin-only methods may adversely affect breastfeeding, however, this was not borne out in this analysis. In the adjusted model of progestin-only methods compared to non-hormonal methods, there was a slight, non-significant trend towards progestin-only methods having a positive impact on breastfeeding duration. These results are consistent with previous literature on later-onset use of progestin-only contraception, after 4-6 weeks postpartum, that show either no effect or better breastfeeding outcomes for progestin-only users.

The physiology of breastfeeding should be equally unaffected by no contraceptive use and by using a non-hormonal method. However the results of this study suggest that caution should be used in selecting the best comparison group for future research on contraceptive use while breastfeeding because the adjusted survival curves and bivariate analyses using these two different comparison groups show different trends. To the extent that the use or non-use of contraception defines distinct populations of women, those who choose not to use contraception may not be the most appropriate comparison group to assess the effects of hormonal contraceptive methods. Women who do not use contraception after birth may represent a very different population than those who use contraception in this period, and, therefore, utilizing the first group as the comparison group may not fully control for factors that are not otherwise captured in the model but are associated with contraceptive use. For instance, studies that have non-users as the control group may not be adequately controlling for partnership status which has been shown to be positively associated with breastfeeding outcomes. (156,158,160) Much of the literature on which the WHO and CDC MECs are based, however, make use of those

who are not using contraception as their control group. Many of these studies report no effect of hormonal methods, particularly progestin-only methods, but the results of this analysis suggest that use of an inadequate control group may be contributing to these results. This may be particularly true if the effect being studied is more subtle or time varying, as is hypothesized for progestin-only methods, since even relatively small mismatches in populations may obscure more subtle associations.

In bivariate analyses, significant differences between women who used progestin-only forms of contraception and those who used non-hormonal methods or no contraception were found. Breastfeeding women using progestin-only methods of contraception were significantly younger than those using non-hormonal methods or no method of birth control. Younger women may have a preference for hormonal contraception, and one may speculate that this could be due to younger women being more familiar with it than other methods or perceive it as being more reliable. Clinicians may assume, or younger mothers may indicate that preventing future pregnancies is more important to them than it is to older women, possibly leading care providers to suggest different methods in an attempt to give these women reliable control over their fertility. Age differences in access to healthcare, may lead to differences in the options available to women of different age groups.

There were also distinct patterns of contraceptive use by race/ethnicity. White mothers were about equally represented across these three contraceptive use categories. In contrast, nearly half of all black mothers used a progestin-only method, while non-hormonal methods were the most common among Hispanic mothers. Black mothers are more likely to use hormonal contraception than other racial and ethnic groups and they

also have the lowest breastfeeding rates. (160,164,165) If clinical reports suggesting that early use of progestin-only methods of contraception negatively impact breastfeeding outcomes are true, the contraceptive use patterns of black mothers may contribute to the health disparity in breastfeeding outcomes. Contraceptive use patterns of Hispanic mothers would be consistent with this possibility since as a group they tend to use non-hormonal methods.

Interestingly, only 22% of Hispanic women did not use contraception compared to nearly a third of black and white mothers. This suggests that pregnancy prevention may be a more important to factor for Hispanic mothers after birth than for white and black mothers. This could be due to a greater desire to prevent pregnancy on the part of Hispanic mothers themselves, but it could also reflect racial bias from healthcare providers or differences in access to contraception based on cost or type of health insurance.

Trends in postpartum contraceptive use in this study highlight the importance of racial and ethnic differences on this topic. While sometimes thought to represent differences in health factors, in this case race and ethnicity are most likely a proxy for social factors that influence a woman's healthcare choices, as well as the options offered to her by her healthcare provider or available to her through health insurance. These factors would likely need to be considered for racial/ethnic patterns of contraceptive use to be changed.

More educated mothers were about equally divided between these three categories, while mothers with a high school only or with less than a high school education were more likely to use contraception after birth. These differences may reflect

differences in socio-economic status and the perceived impact of another pregnancy either by the mother herself or from those around her including healthcare providers. Pregnancy prevention may be more important to less educated mothers, but these trends could also reflect differences in access to care, perhaps with greater access for less educated women via public health programs. Bias from healthcare providers could also play a role, either consciously or unconsciously assuming that more children would be undesirable for less educated women.

Pregnancy wantedness is not significantly associated with the type of contraceptive used among mothers who initiated breastfeeding, however, a suggestive trend towards contraceptive use among women whose pregnancies were unwanted or mistimed is present; 22.5% of these women chose not to use contraception after birth. In contrast, 32.7% of women for whom all pregnancies would be wanted went without contraception after birth, and 29.7% of women whose pregnancies were wanted and timely did not use contraception. Reporting of mistimed or unwanted pregnancies was much lower in this sample than reported nationally, suggesting that this factor is likely underreported in this sample. The trend towards higher contraceptive use after mistimed or unwanted pregnancies suggests that a prior unwanted or mistimed pregnancy may influence contraceptive use after that birth, and may be an important factor to consider for research and clinical practice.

Mothers with older children were much more likely to use a progestin-only method rather than a non-hormonal method after birth, indicating that family size influences contraceptive use in the postpartum period. Clinicians may assume that pregnancy prevention is a priority for mothers with more than one child and therefore

steer them towards methods with higher efficacy without fully considering the implications for breastfeeding. Having older children may also be a proxy for the mother having achieved her desired family size, a factor that was not available in this dataset. A woman who has achieved her desired family size may be more motivated to prevent future pregnancies, shifting her decision making balance towards pregnancy prevention and away from breastfeeding protection. If so, this would indicate a need for better information about and promotion of types of contraception that are compatible with breastfeeding targeted at women who feel they have completed their child-bearing.

Breastfeeding-related hospital practices were evaluated to assess whether a breastfeeding-friendly hospital setting had an impact on breastfeeding-supportive contraceptive choice. Timing of breastfeeding initiation, receipt of a formula sample bag, and the number of other breastfeeding-related hospital practices experienced by the mother were not associated with type of contraception used. However, mothers who had a visit by an LC or other breastfeeding support person were most likely to use a progestin-only method (37.8%) while those who did not report being visited by a breastfeeding specialist were most likely to use a non-hormonal method (40.5%). This is surprising since, as a group, LCs have been advocating for more caution in using progestin-only methods while breastfeeding. This may simply reflect that women who are experiencing breastfeeding difficulties are more likely to receive a breastfeeding support visit and more likely to initiate contraceptive use. It could also reflect higher rates of breastfeeding challenges for those who initiate contraceptive use immediately after birth, an possibility that cannot be addressed with this sample because no information about timing of contraceptive use was collected. Given that the current CDC

medical eligibility criteria for postpartum contraceptive use indicates that progestin-only

methods are compatible with breastfeeding, these results could also reflect better

education about the CDC recommendations among women who have received a

breastfeeding support visit. Moreover, while many LCs in private practice may be

cautious about recommending progestin-only methods based on their clinical observation,

this variable included other support staff who may be less knowledgeable about these

issues. It is possible that in the hospital setting more staff may be adhering to CDC

recommendations that suggest that early use of progestin-only methods are compatible

with breastfeeding.

Whatever the cause, differences in contraceptive use after birth follow similar

patterns to breastfeeding outcomes, suggesting that the two issues may be related as

proposed by clinicians. There is a need to understand the association between the type of

contraceptive used while breastfeeding and breastfeeding outcomes to ensure that

contraceptive use is not contributing to health disparities in breastfeeding and the health

consequences of breastfeeding. While the results of the survival analysis did not show an

effect of progestin-only methods, the effect of early use of progestin-only methods could

not be differentiated from later use because this dataset did not include information on

timing of contraceptive use. Consequently, these results should not be interpreted to mean

that progestin-only methods are compatible with breastfeeding.

LIMITATIONS

An important limitation of this study is the lack of information about the timing of initial contraceptive use. Biological models suggest that early introduction of progestogenic contraception after birth may disrupt breastfeeding establishment, while later introduction may have no effect or a supportive effect on breastfeeding outcomes. If this is the case, this study would not be able to distinguish these effects since all women who used progestin-only methods were grouped together, regardless of early or late onset of use. The available data did not allow evaluation of the intensity or exclusivity of breastfeeding, and therefore assessment of more nuanced breastfeeding outcomes could not be carried out. Examination of these important indicators of breastfeeding success would help to clarify the effects of progestin-only contraception on breastfeeding.

The high amount of censored data in this sample (69.0%) may limit the power to detect differences in breastfeeding duration between contraceptive use groups. While duration of breastfeeding is unavailable for these women, it is informative that they were able to breastfeed as long as they reported, and that this occurred in the context of their reported contraceptive use. Moreover, censoring would likely be a less significant issue at earlier time-points, which is the time frame of most interest since women may be a more vulnerable to breastfeeding cessation as the biology and behavior of breastfeeding are being established. This is also the time frame in which progestin-only methods are hypothesized to have the greatest impact. Censoring could bias the sample if it was associated with the outcomes, breastfeeding or contraceptive use. This sample was selected at random from birth certificate data, limiting this possibility; however, if

availability by landline telephone or willingness to participate in a telephone survey was correlated with breastfeeding outcomes or contraceptive use this could introduce bias.

This analysis is also vulnerable to the possibility that women began using contraception after breastfeeding cessation. However, most women in this sample were still breastfeeding, and their achieved duration was accomplished in the context of their contraceptive use or non-use. Moreover, the infants in this sample were relatively young, which further limits this possibility of reverse causation.

Intensity or exclusivity of breastfeeding could not be evaluated in this sample, and therefore could not assess these more nuanced breastfeeding outcomes. This is unfortunate, since exclusivity is a relevant outcome of interest in relation to milk supply, a potential point of impact for exogenous hormones like those in hormonal contraception.

In the United States, there is a large drop-off in breastfeeding rates during the first year, which could affect the ability of this study to detect associations between contraceptive use and breastfeeding outcomes. If factors such as social, demographic, and healthcare are more important to breastfeeding cessation than biological factors, it may be difficult to detect the biological impact of contraceptive use if there is residual confounding. Unmeasured factors that contribute to breastfeeding cessation could be wrongly attributed in this study as an effect of contraceptive use. The use of propensity scores is intended to address the multi-faceted nature of this topic area and, therefore, address this concern.

Confounding is a particular problem in this area of work as seen by the significant demographic differences between the users of different types of postpartum contraception. Similarly, there were significant demographic differences between those

who did and did not initiate breastfeeding and by duration (reported for this sample in chapter 2). However, propensity score weighting was able to adequately balance the demographic characteristics of women in the different contraceptive use categories. This suggests that this technique may be useful in controlling for confounding and examining causality in future studies on contraceptive use while breastfeeding.

A limitation of propensity scores is the assumption of no unmeasured confounders. Breastfeeding and contraceptive use both have complex etiologies that include social, psychological, biological, and healthcare factors. This dataset is unusual in the breastfeeding literature for the number and quality of breastfeeding and contraception related questions it asks. However, information on timing and sequencing of contraceptive use, partnership status, social support for breastfeeding, maternal depression, urbanicity, and maternal obesity, and others were not available in this dataset. To the extent that the factors available are more proximal to the outcome, they may serve as adequate proxies for these and other unmeasured factors and mitigate the vulnerability of using this statistical approach. Furthermore, it should be noted that the assumption of no unmeasured confounders is also present for other common statistical approaches, and therefore not specific to this analytic design.

The sample population was selected from North Carolina Birth Certificates and contacted by telephone. Differences in the covariates and in contraceptive use may exist between those available by landline telephone and those who cannot be reached by this means including those who do not have a landline telephone. For instance, people who use cell phones exclusively would not be available by this means, and this could disproportionately exclude younger, poorer, and more transient mothers from the sample

leading to sample bias. If willingness to participate in a telephone survey were not randomly distributed, the sample would also be biased. These concerns are addressed in two ways. First, the random selection process using birth certificate records provides an unbiased foundation for sample selection. In addition, many measures were undertaken to contact potential subjects including multiple contact attempts, contact at different times of the day and week, and contact attempts over several months. Furthermore, if the potential participant declined, efforts were made by specially trained personnel to convince the potential study subjects to participate.

The retrospective study design relied on maternal self-report and is vulnerable to recall bias which would be more likely to affect transient factors and factors with perceived positive or negative connotation. For example, unwanted and mistimed pregnancies are reported less often in this sample than has been found in national data. Mothers may be reluctant to tell the interviewer that their pregnancy was unwanted or mistimed, and she might also unconsciously re-evaluate the wantedness of her pregnancy as she begins to bond with her baby. Similarly, a mother's recall of her intention to breastfeed may change in light of her actual experience of breastfeeding. Reporting of hospital practices may be also be bias by events that happen later, and mothers could simply not remember what occurred during that time. Some may not even know whether and when events happened, which could be correlated with maternal or infant health. Finally, reporting of contraceptive use may be subject to recall bias, especially if more than one method has been used since birth. This sample is likely comparable to other studies in the field of breastfeeding research since results from this study are consistent with other breastfeeding studies on covariates commonly reported in the literature.

Non-random missing data could lead to sample bias, however the amount of missing data for the variables used in the model was 1%-3%, which is very low. Few factors in the model were significantly associated with contraceptive use suggesting that this model was missing variables that influence the use of contraception after birth. For instance, partnership status, whether the mother is sexually active, and whether she has achieved her desired family size could all be important factors in using contraception, but were not available in the dataset. Timing of contraceptive use would also have been useful to provide a more complete description of postpartum contraception. This is particularly true for women who reported using more than one method since birth because the timing, order and duration of these methods were unknown. However, the sample is unusual in that is has information about breastfeeding outcomes alongside information about contraceptive use, enabling analysis of contraception use during breastfeeding. Few analyses of postpartum contraceptive use have been carried out in adult populations, so this study also contributes to the literature by describing factors associated with contraceptive use in this large and meaningful demographic.

CONCLUSION

No effect of progestin-only contraceptive use on breastfeeding duration was found when compared to either non-hormonal methods of birth control or using no method. These results are limited by the lack of information on the timing of initiation of use. In particular, early use, i.e., immediate postpartum, could not be distinguished from later use. The use of propensity scores in our survival analysis successfully matched our study

groups, and may be a technique useful for future work in the field. This is particularly

compelling given the strong differences identified between women who use different

types of contraception after birth.

	Total	Percentage of Total
Table 14: Characteristics of the Population of Women Who Initiated Breastfeeding From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11. (N=1,141). Limited to Women Who Reported Using Progestin-Only, Non-hormonal, or No Method of Birth Control		
	1,141	100%
Maternal Age (years)		
Mean	30.6	
Median	31	
Race/ Ethnicity		
Non-Hispanic White	750	65.7%
Non-Hispanic Black	116	10.2%
Hispanic	242	21.2%
Other	33	2.9%
Maternal Education		
Less than High School	138	12.1%
High School	289	25.3%
College	461	40.4%
Graduate School	253	22.2%
Pregnancy Wantedness		
Wanted at This Time	707	62.0%
Not Wanted / Mistimed	284	24.9%
All Pregnancies Wanted	150	13.1%
First Child		
No	385	33.7%
Yes	756	66.3%
Baby's Gender		
Female	603	52.8%
Male	538	47.2%

NICU Stay		
no	1,014	88.9%
yes	127	11.1%
Intention to Breastfeed		
No	24	2.1%
Yes	1,117	97.9%
Timing of Initiation		
< 1 Hour	518	45.4%
1 to <2 Hours	225	19.7%
2 to 24 Hours	281	24.6%
> 24 Hours	117	10.3%
Received Formula Sample Bag		
No	278	24.4%
Yes	863	75.6%

Table 15: Percentage of the Sample at Each Month Who are Still Breastfeeding, Among Women Who Initiated Breastfeeding (N=1,319). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11 and Limited to Women Who Reported Using Progestin-Only, Non-hormonal, or No Method of Birth Control.

	Not Breastfeeding n (%)	Breastfeeding n (%)
1 Month	115 (10.1%)	1,026 (89.9%)
2 Months	242 (21.2%)	899 (78.8%)
3 Months	454 (39.8%)	687 (60.2%)
4 months	862 (75.5%)	279 (24.5%)
5 Months	1121 (98.2%)	20 (1.8%)
> =6 Months	1132 (99.2%)	9 (0.8%)

Table 16a: Characteristics of the Population (continuous variables) by Method of Postpartum Contraceptive Use (N=1,319). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11 and Limited to Women Who Initiated Breastfeeding, and Who Reported Using Progestin-Only, Non-hormonal, or No Method of Birth Control.

	No Method n (%)	Non-Hormonal n (%)	Progestin-Only n (%)	Total n
Total	323 (28.3%)	395 (34.6%)	423 (37.1%)	1,141(100%)
Maternal Age* (years)**				
Mean	31.8	31.5	28.9	30.6
Median	32	32	30	31
Infant Age at Time of Interview				
Mean	3.28	3.23	3.27	3.26
Median	3	3	3	3
Hospital Practices				
Mean	3.9	3.8	3.9	3.9
Median	4	4	4	4
*** p<0.001 ** p<0.01 * p<0.05				

Table 16b: Characteristics of the Population by Method of Postpartum Contraceptive Use (N=1,141). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11 and Limited to Women Who Initiated Breastfeeding, and Who Reported Using Progestin-Only, Non-hormonal, or No Method of Birth Control.

	No Method n (%)	Non-Hormonal n (%)	Progestin-Only n (%)	Total n
Total	323 (28.3%)	395 (34.6%)	423 (37.1%)	1,141(100%)
Race/ Ethnicity**				

Non-Hispanic White	224 (29.9%)	254 (33.9%)	272 (36.3%)	750
Non-Hispanic Black	36 (31.0%)	25 (21.6%)	55 (47.4%)	116
Hispanic	54 (22.3%)	101 (41.7%)	87 (36.0%)	242
Other	9 (9.1%)	15 (45.5%)	9 (9.1%)	33
Maternal Education*				
Less than High School	28 (20.3%)	58 (42.0%)	52 (37.7%)	138
High School	70 (24.2%)	101 (34.9%)	118 (40.8%)	289
College	146 (31.7%)	148 (32.1%)	167 (36.2%)	461
Graduate School	79 (32.3%)	88 (34.8%)	86 (34.0%)	253
Pregnancy Wantedness				
Wanted at This Time	210 (29.7%)	241 (34.1%)	256 (36.2%)	707
Not Wanted / Mistimed	64 (22.5%)	99 (34.9%)	121 (42.6%)	284
All Pregnancies Wanted	49 (32.7%)	55 (36.7%)	46 (30.7%)	150
First Child*				
No	108 (28.3%)	106 (27.7%)	171 (44.4%)	385
Yes	215 (28.4%)	289 (38.3%)	252 (33.3%)	756
Baby's Gender				
Female	171 (28.4%)	202 (33.5%)	230 (38.2%)	603
Male	152 (28.3%)	193 (35.9%)	193 (35.9)	538
NICU Stay				
no	290 (28.6%)	357 (35.2%)	367 (36.2%)	1,014
yes	33 (26.0%)	38 (29.9%)	56 (44.1%)	127

Intention to Breastfeed				
No	8 (33.3%)	5 (20.8%)	11 (45.8%)	24
Yes	315 (28.2%)	390 (34.9%)	412 (36.9%)	1,117
Timing of Initiation				
< 1 Hour	162 (31.3%)	172 (33.2%)	184 (35.5%)	518
1 to <2 Hours	53 (23.6%)	84 (37.3%)	88 (39.1%)	225
2 to 24 Hours	77 (27.4%)	94 (33.5%)	110 (39.1%)	281
> 24 Hours	31 (26.5%)	45 (38.5%)	41 (35.0%)	117
Received Formula Sample Bag				
No	83	87	108	278
Yes	240	308	315	863

*** p<0.001   ** p<0.01   * p<0.05

Table 17: Population Characteristics for Statistically Significant Individual Hospital Practices that Comprise the Ordinal Variable "Hospital Practices" by Method of Postpartum Contraceptive Use (N=1,141). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11 and Limited to Women Who Initiated Breastfeeding, and Who Reported Using Progestin-Only, Non-hormonal, or No Method of Birth Control.

	No Method n (%)	Non-Hormonal n (%)	Progestin-Only n (%)	Total n
LC Visit*†				
No	56 (25.5%)	89 (40.5%)	75 (34.1%)	220
Yes	267 (29.0%)	306 (33.2%)	348 (37.8%)	921

* p<0.05
† This variable is included in the ordinal "Hospital Practices" variable and is not included as a separate variable in the analyses.

Table 18: Hazard of Breastfeeding Cessation as a Function of Type of Contraceptive Used (N=1,141). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11 and Limited to Women Who Reported Using Progestin-Only, Non-hormonal, or No Method of Birth Control.

	Hazard Ratio	Lower 95% CL	Upper 95% CL	Likelihood ratio test	Sample Size	Percent censored
Progestin-only methods	referent					
No Method	0.92	0.71	1.19	p>0.542	746	70.4%
Non-hormonal methods	0.85	0.67	1.09	p>0.212	817	69.3%

*Adjusted for maternal age, race/ethnicity, maternal education, pregnancy wantedness, parity, baby's gender, NICU stay, intention to breastfeed, timing of initiation, receipt of a formula sample bag, and hospital practices through the propensity score

Figure 6: Survival Plots of Breastfeeding Duration by Type of Contraception Used.
From a Survey Evaluating the Period of Purple Crying intervention program, 2010-11, and limited to women who initiated breastfeeding. Curves are Adjusted for maternal age, race/ethnicity, maternal education, pregnancy wantedness, parity, baby's gender, NICU stay, intention to breastfeed, timing of initiation, receipt of a formula sample bag, and hospital practices through propensity score weights.
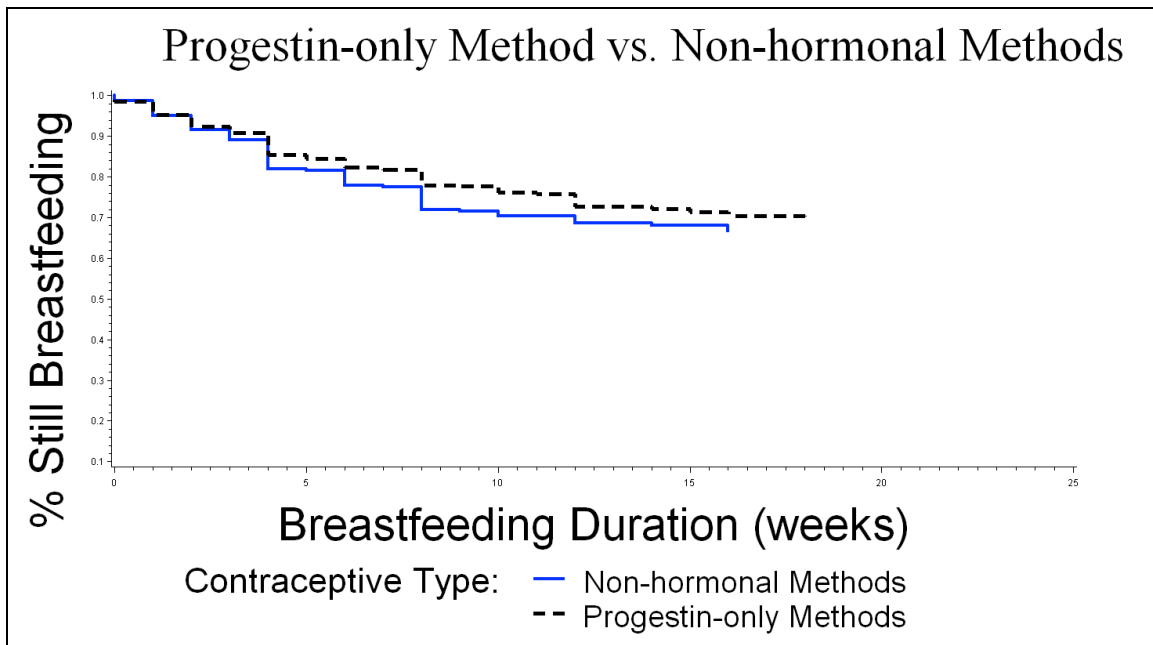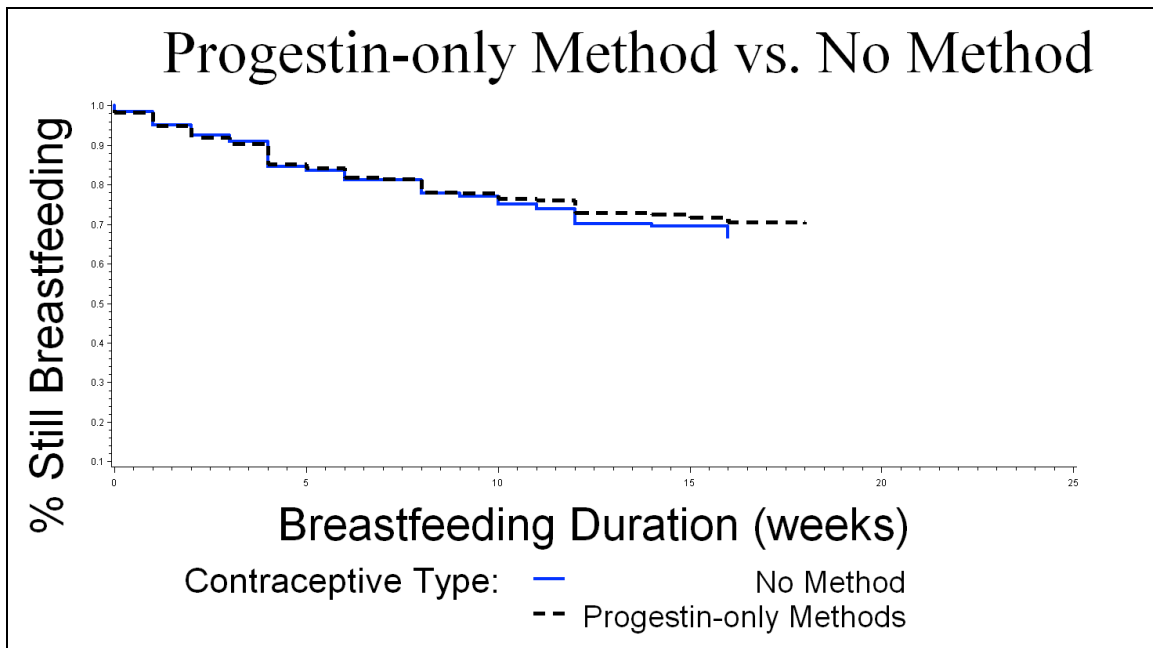
CHAPTER V: EFFECT OF COMBINED ESTROGEN/PROGESTIN METHODS OF BIRTH CONTROL ON BREASTFEEDING DURATION

INTRODUCTION

Breastfeeding is the optimum form of infant feeding according to the World Health Organization (WHO) and the American Academy of Pediatrics (AAP). (1,2) Breastfeeding carries short and long term advantages for both the baby and mother, and exclusive breastfeeding is recommended by both the AAP and WHO for the first six months of life with continued breastfeeding afterwards as solids are introduced. (3) The Healthy People 2010 initiative of the US Department of Health and Human Services set a goal for the country of at least 75% breastfeeding initiation and at least 50% breastfeeding continuation at 6 months. (4) By 2010, 76.9% of mother-infant dyads initiated breastfeeding and 47.2% were nursing at six months, nearly meeting the Healthy People 2010 target. (5) However, only 16.3% were breastfeeding exclusively at six months, the recommendation from both the WHO and AAP. Healthy People 2020 set breastfeeding goals for the current decade of 81.9% initiation, 60.6% continuation at six months, and 25.5% exclusive breastfeeding at six months. (6) It is likely that in order to meet these ambitious targets new programs and policies will be needed. This project aims to inform that process by providing up to date information about breastfeeding and contraceptive use in the United States.

The health impact of breastfeeding is extensively reported in the literature. Breastfed infants have lower rates of a wide range of illnesses including ear infections, bacterial meningitis, urinary tract infections, intestinal infections, diarrhea, and childhood cancers. (7-15) Lower rates of sudden infant death syndrome, asthma, obesity, and diabetes are also seen in children who are breastfed. (16-24) Childhood cognitive development may also be enhanced by breastfeeding. (25-27)

Mothers also experience better immediate and long-term health outcomes with breastfeeding. Women who breastfeed have less postpartum blood loss and are more likely to experience rapid uterine involution. (28) They also have lower rates of breast and ovarian cancer and fewer hip fractures and osteoporosis later in life. (29-33)

The health implications of postpartum family planning are well documented as well, and also have serious implications for both maternal and infant health by affecting inter-birth interval. Women with short birth intervals, less than six months, were found to have higher risk of maternal mortality (odds ratio 2.54; 95% CI 1.22-5.38), third-trimester bleeding (1.73; 142-2.24), premature rupture of membranes (1.72; 1.53-1.93), puerperal endometritis (1.33; 1.22-1.45), and anemia (1.30; 1.18-1.43). (43) For those with previous Cesarean deliveries, birth intervals of less than 18 months were associated with a higher risk of uterine rupture, 2.25% vs. 1.05% for intervals of 19 months or longer. (44)

The impact on long-term health for individuals and on healthcare costs as a nation is, therefore, large. (34) Infant morbidity and mortality related to the low prevalence of meeting the 6 month exclusive breastfeeding recommendations of the American Academy of Pediatrics alone is estimated to cost the United States (US) $13 billion

199

annually. (35) Similarly, Trussell et al. estimate that the annual cost of unintended pregnancy in the US is $4.5 billion. (41) The burden of unplanned pregnancies falls disproportionately on ethnic and racial minorities and those with less education, the same groups that tend to have lower financial means and access to healthcare. Between 1994 and 2001, the rate of unintended pregnancy among white women was estimated to be 35 per 1,000, while black women had 98 per 1,000 and Hispanic women had 78 per 1,000. (39) Education is also strongly associated with unintentional pregnancy, with 26 per 1,000 for women with college degrees, and 76 per 1,000 for women without a high school degree. Contraceptive use follows similar racial and education patterns and is thought to be both a response to and a cause of these differences. (40)

The health and economic impact of breastfeeding and family planning highlight the importance of access to effective family planning methods that are compatible with breastfeeding. The biological pathways that establish and maintain lactation are responsive to endogenous estrogen and progesterone. Moreover, exogenous estrogens are reported to reduce milk supply and progestins are suspected to as well. The WHO and Centers for Disease Control (CDC) have developed Medical Eligibility Criteria (MEC) for contraceptive use in the breastfeeding population. Both organizations base their recommendations on the same body of scientific literature, however, they come to different conclusions about the overall safety and timing of use of hormonal contraception. (98,99,102) Much of this literature is more than twenty years old and the research was conducted in settings like Egypt and Chile where patterns of breastfeeding and infant care are very different than in the US. Moreover, the statistic methods used often did not address issues of confounding and bias.

In spite of the potential negative effects on breastfeeding reported by both the WHO and CDC, a report from 1994 showed that many mothers in that era strongly preferred to use combined hormonal contraceptives. (98,99,108) It is not known whether today's mothers have the same preference, and given the greater public awareness of the benefits of breastfeeding for both mother and baby, generalizing from 1994 is limited. However, many of the reasons cited by mothers in 1994 are still relevant today, familiarity with the method, beneficial effects for menstrual cycling, and control of bleeding.

This study aims to elucidate the impact of combined estrogen/progestin methods of birth control on breastfeeding duration in a US context, and to employ statistical methods to more fully account for differences between women who use different forms of contraception. It addresses several of the fundamental issues with the CDC/WHO literature because it is both recent, conducted in 2010-1, and US based, i.e., North Carolina. North Carolina falls in the middle of the spectrum of US states in terms of breastfeeding initiation and continuation, has a variety of urban and rural areas, and has immigration from other parts of the country and beyond, mixing social norms from other regions. Geophysically, socio-culturally and economically, there is a diversity of settings within the state that encompass a wide spectrum of the American social context. Politically, the electorate splits closely between major parties. There is a sizable minority of African Americans and Hispanics. Together, this makes North Carolina an informative setting to explore the current state of breastfeeding in the US, and well suited to addresses this question.

MATERIALS AND METHODS

Subjects

A telephone survey of new mothers in North Carolina was carried in from April 2010 to March 2011 with a main purpose of assessing breastfeeding outcomes. About 2,000 potential study subjects were drawn from birth certificate data on the approximately 130,000 births in the state each year. Landline telephone numbers were back-matched from the birth certificates and attempts were made to contact new mothers in those households. Only those with working telephones and residing in the state of North Carolina were eligible for the survey. 1,669 women agreed to participate in the study and all but 25 completed the one-time phone interview, which was carried out in either English or Spanish by the female parent or legal guardian. Over-sampling of certain sub-populations was carried out to ensure sample size for infants less than two months and between two and three months of age, maternal Hispanic ethnicity, urban/rural location, and hospital size for the birth. The birth certificate information was not retained, and no verification was done to ensure that the respondent was the actual mother referenced on the birth certificate, with the exception that if more than one child in the household met the study criterion, the child referenced on the birth certificate was referenced in the study.

For this analysis, looking at the effect of postpartum exposure to contraception on breastfeeding, the analytic sample was limited to women who initiated breastfeeding (1,404), regardless of her breastfeeding duration. Only participants with complete

information on all study variables were included in the analysis (N=1,319), 93.9% of the eligible participants,

STATISTICAL ANALYSES

Chi squared and Kruskal Wallis tests were performed to assess differences between women who used each type of contraceptive in the postpartum period. Women who were still breastfeeding at the time of the interview were right censored in our analysis, whereas those who had ceased to breastfeed prior to the interview had actual durations of breastfeeding.

A Kaplan-Meier survival analysis of breastfeeding duration was performed as described by Cole and Hernán using inverse probability weights based on propensity scores for postpartum contraceptive use. (207) The propensity scores for type of contraceptive used in the postpartum time period were calculated based on maternal and infant demographic variables (maternal age, maternal education, race/ethnicity, baby's gender), psychosocial factors (pregnancy wantedness, intention to breastfeed), health factors (infant NICU stay, parity, and an interaction term for NICU stay and parity), and breastfeeding-related maternity care practices: timing of breastfeeding initiation, receipt of a formula sample bag at hospital discharge, an ordinal variable for the number of Hospital practices experienced by the mother, and an interaction term for maternal age and hospital practices. In order to more readily evaluate the results, the same covariates were used to create the propensity scores for each analysis.

The model was developed beginning from a full model that included all variables known from the literature to be associated with breastfeeding outcomes and which were available in the sample. To assess the best way to code variables where more than one logical option existed, nested models were compared using likelihood ratio tests with a cut-off of $p<0.05$. Non-nested models were compared using Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC), and parameters that were neither statistically significant at the $p<0.05$ level nor crucial factors from the literature were removed from the model. Covariates that were predictive in any model were retained.

Comparison of the distribution of propensity scores for the treatment groups was used to assess whether this method adequately controlled for differences between the groups. Furthermore, an analysis of the area of common support, that is the portion of the sample for which propensity scores exist in both groups, was made by trimming the propensity scores for each group at 1% and 99% cut-offs and restricting the analysis to innermost points of the two groups. (218,219) A visual assessment of the propensity score weighting for the two groups showed some area without overlap between exposed and control groups, but an analysis of the area of common support, that is the portion of the sample for which propensity scores exist in both groups, (innermost 1% cut-offs) gave very similar results.

In separate analyses, comparison was made between combined estrogen/progestin methods and progestin-only methods, non-hormonal methods, and no method of contraception. Statistical Analyses were performed using SAS software version 9.2.

MEASURES

Demographic characteristics. Infant and maternal demographic characteristics were collected during the interview, and only information obtained in the interview was retained in the dataset. Study participants were asked about the infant's gender and race/ethnicity, and their own age, educational level, family household income, and county of birth.

Infant gender, male/female, was asked directly in the interview. The infant's race/ethnicity was classified for the purposes of this study using three questions from the interview. Mothers were asked to identify the race of their infant, and allowed to choose as many categories as they felt applied. They were asked separately about the infant's Hispanic ethnicity. Any child identified as being Hispanic was classified as Hispanic for the purposes of this study, regardless of any racial identification. Among non-Hispanics, infants with only one race reported on the survey were identified as that race. Among the remaining study subjects who were reported to be mixed-race, any infant identified as being "white" in a separate question about whether the parent considered the child white, was identified as "non-Hispanic white." Next, those who were reported to be mixed-race with one race being black were identified as "non-Hispanic black." All remaining study subjects were classified as, "other," which included Asian, Pacific Islander, Hawaiian, Alaskan native, and Native American, as well as, anyone who identified their child as "other".

Maternal age was recorded in whole years, coding it as a continuous or ordinal variable with 5-year age-bins was assessed to determine which fit the data best by using

Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC) tests. Continuous coding was determined to be most appropriate here and the data were mean-centered for ease of interpretation of the model. In addition, the assumption of linearity was tested by exploring a quadratic term for maternal age, and found to be non-significant.

Information about the county of birth was organized by region of the state in accordance with the boundaries used for programmatic, funding, and demographic uses by the state of North Carolina. Those regions are Western/Mountain, Piedmont, and Eastern/Coastal. This variable was not significant in any model and a likelihood ratio test was used to determine that it should be dropped from the final model.

Health factors. Neonatal intensive care unit (NICU) stay by the infant was asked directly in the interview as a yes/no dichotomous question. Mothers were also asked whether there were older biological siblings of the child in the study. First-born status was extrapolated from this information.

Psychosocial factors. Mothers were asked about their pregnancy intention using the WHO categories for pregnancy wantedness: wanted at this time, wanted not at this time, not wanted, and all pregnancies are wanted. We combined the middle two categories into a single mistimed/unwanted category for our analysis in order to account for the small cell size of unwanted pregnancies.

The mother's pregnancy and breastfeeding intention were assessed in the interview. Women were asked about their pre-birth intention to breastfeed (dichotomous

yes/no) and their intended duration. A high level of missing data for the intended duration question and strong co-linearity between these variables led us to choose the dichotomous variable for this study.

Hospital practices. Mothers were asked about their experience of the seven maternity care related practices identified in the WHO Ten Steps to Successful Breastfeeding. Anecdotal evidence suggests that many hospitals in North Carolina implement a restriction on giving out formula sample bags before they implement the other steps. (210) Therefore, we analyzed this step separately. Timing of breastfeeding initiation was also analyzed independently since this practice was seen to have a significant association with breastfeeding duration in a multivariate analysis. The other five practices were analyzed both individually and as a group using an ordinal variable for hospital practices that was coded zero to five for the number of practices experienced by the mother. The practices were not specific to the Ten Steps, but are aspects of specific steps. These practices are immediate skin-to-skin contact between mother and infant after birth (Step 4), rooming-in at least 22 of every 24 hours (Step 7), visit by a Lactation Consultant (LC) or breastfeeding support person (proxy for Step 5), observation of a feeding by an LC or breastfeeding support person (also Step 5), and all facility staff supporting the mother's decision on infant feeding (also Step 5).

Postpartum contraceptive used. Mothers were asked about the methods of contraception they had used since the baby's birth, and were allowed to identify as many methods as applied. Responses were classified into four categories. Where more than

207

one method was reported, the woman's use was classified in the category most contra-indicated for breastfeeding. That is, in this order: combined estrogen/progestin, progestin-only, non-hormonal, and no method of contraception.

Breastfeeding. Among those who had stopped breastfeeding, breastfeeding duration was calculated based on the mother's report of the infant's age at cessation. Among those still breastfeeding at the time of the survey, the breastfeeding duration was right censored in the analysis, indicating that her duration was not a final duration, but rather, a 'duration-to-date.' For these women, duration was calculated based on the date of the interview and the baby's birth date reported by the mother during the interview. Ages were converted to weeks by dividing by 7 and rounding to the nearest whole number.

Interaction terms. An exploratory analysis of interactions between variables was carried out in a separate analysis of direct associations between the independent variables and breastfeeding duration using a Cox proportional hazards model of breastfeeding cessation. Interactions between the variables for hospital practices and maternal age, timing of breastfeeding initiation, NICU stay, infant gender, and intention to breastfeed were tested. In addition, interaction terms for first-born status and NICU stay and for the wantedness dummy variables were explored, as well as breastfeeding intention and infant gender. An interaction between infant NICU stay and first-born status was found to be significant in some analyses, and was, therefore, kept in the model for all regressions. An interaction between the mother's age and a proxy for all hospital practices developed as an ordinal variable was significant and remained in the model. Interactions between the

208

individual hospital practices and maternal age were also explored, and a likelihood ratio test was used to determine that the ordinal variable and ordinal variable-maternal age interaction term were the best for the model.

Missing Data. All variables in the model had low levels of missing data, between one and three percent, except family household income and intended breastfeeding duration.

The relatively high levels of missing data for intended breastfeeding duration raised concerns that the information may not have been missing at random, but rather, could represent differences in maternal knowledge about breastfeeding, or interest in or commitment to breastfeeding. Therefore, the mother's intended duration was not used in the model and the dichotomous variable for breastfeeding intention was used in the model instead.

We performed a likelihood ratio test on the model with and without household income and determined that the simplified model was preferable. Moreover, using forest plots of the other parameter estimates we determined that none of the other associations shifted beyond their confidence intervals when income was included in the model. Therefore, income was dropped from the model, and a complete case analysis of only those participants with complete data was performed.

IRB. This study received IRB approval from the University of North Carolina, Chapel Hill.

RESULTS

Description of the population by Univariate and Bivariate Analyses

The sample included 1,319 of women who had initiated breastfeeding and also had complete information on all covariates in the analysis. The mean age in the population was 30.3 years, with a minimum of 14 and a maximum of 46 (Table 19). The sample was 66.4% non-Hispanic white, 10.1% non-Hispanic black, 20.7% Hispanic, and 2.8% other. There were slightly more female infants (51.9%), and 11.2% of infants spent time in the NICU compared to about 6.7% nationally. (211). First time mothers made up 64.0% of the population. Mothers with less than a high school degree made up 11.9% of the population, 26.2% had a high school education, 40.6% had a college degree, and 21.3% had a graduate degree. The mean infant age at the time of the interview was 3.29 months (Table 21a), and across the range of infant ages there was a distribution of breastfeeding status (Table 20). The most common form of contraception in this population were progestin-only methods (32.1%), follow by non-hormonal methods (29.9%), no contraceptive use (24.5%), and combined estrogen/progestin methods (13.5%) (Table 21a).

When comparing users of different types of contraceptive methods in the postpartum period using bivariate analysis, statistically significant differences were found for maternal age, race/ethnicity, maternal education, first-born child, and visit by an LC or breastfeeding support person (Tables 21a and 21b). No statistically significant difference in pregnancy wantedness, baby's gender, infant NICU stay, intention to breastfeed, timing of initiation, receipt of a formula sample bag at hospital discharge, or

the number of breastfeeding-related hospital practices received was found among contraceptive use categories.

Mean maternal age was different across categories of contraceptive use (Table 21a). The mean age for hormonal methods, either progestin-only (28.9) or combined estrogen/progestin (28.5) was several years younger than for non-hormonal methods (31.5) or using no method of contraception (31.8). There were also statistically significant differences in contraceptive method used by race/ethnicity (Table 21b). About 31.1% of Non–Hispanic white women used a progestin-only method; they used non-hormonal methods or no contraception less often (29.0% and 25.6% respectively). In contrast, a higher percent of non-Hispanic black mothers (41.4%) used a progestin-only method. Very few used a non-hormonal method, (18.8%) but 27.1% of non-Hispanic black mothers did not use birth control during this period of time. Hispanic mothers were most likely to use non-hormonal methods (37.0%), and least likely to go without contraception (19.8%). All race/ethnic groups had low rates of usage for combined estrogen/progestin methods.

Differences were found between women by educational attainment as well (Table 21b). Women with less than a high school education were mostly likely to use a non-hormonal method of contraception in the postpartum period (36.9%), women with a high school degree were most likely to use a progestin-only method (34.2%), while women with college or graduate degrees had similar usage rates for three categories: progestin-only, non-hormonal and no method.

Parity was strongly associated with the type of contraceptive used after birth (Table 21b). Nearly equal percentages of women with first-born and subsequent children

did not to use contraception after birth (25.5% and 22.7% respectively). However, first time mothers were much more likely to use a hormonal method, 36.0% for progestin-only and 19.0% for combined estrogen/progestin, over a non-hormonal method (22.3%). In contrast, 10.4% of multiparous women used a combined estrogen/progestin method, and their top choice was non-hormonal contraception (34.2%).

There was no statistically significant difference in contraceptive use among women based on the number of breastfeeding-supportive hospital practices they experienced, however, one of the individual practices included in this composite measure did show a significant difference; among those visited by an LC or other breastfeeding support person, more women chose progestin-only methods (32.3%) than non-hormonal (28.4%), no method (24.8%) or combined estrogen/progestin methods (14.4%) (Table 22). In contrast, among those who did not have an LC or other breastfeeding support person visit them, the most common form of contraception was a non-hormonal method (36.6%). Analyses of individual hospital practices showed no significant association between immediate skin-to-skin contact, rooming-in, observation of a feeding by an LC or other breastfeeding support person, or facility staff supporting the mother's infant feeding choice and type of contraceptive used after birth.

Survival Analysis of Breastfeeding Duration by Postpartum Contraceptive Use

The association between type of contraception used after birth and breastfeeding duration was explored using a Cox proportional hazards model with propensity score based inverse probability weights used to control for differences between groups of contraceptive users.

In the comparison between combined estrogen/progestin methods and no method of contraception, the breastfeeding of 501 subjects was modeled, of which 55.5% were right censored (Table 23). After propensity score adjustment, the hazard of breastfeeding cessation for users of combined hormonal contraception was 3.07 (95% CI 2.39, 3.96) when compared to non-users, which was a shift from the crude results of 3.20.

Goodness of fit for the propensity score matching between those who used combined estrogen/progestin contraceptive methods and those who did not use contraception was assessed using histograms of the distribution of propensity scores grouped by contraceptive type. Visual assessment showed a moderately good fit (Appendix 2). Analysis of the area of common support using 1% cut-offs gave consistent results with the un-restricted analysis (Appendix 1).

The breastfeeding outcomes of 573 subjects were analyzed in a comparison of combined estrogen/progestin method users and users of non-hormonal contraceptive methods. Right censoring was present for 56.0% of the study subjects. In the crude analysis, combined hormonal methods had hazard ratio of 2.05 compared to non-hormonal methods, whereas, after adjustment their hazard of cessation was 2.76 (95% CI 2.19, 3.49). Comparison of the histograms for the inverse probability weights of the two study populations showed substantial overlap, and analysis of the area of common support using a 1% cut-off gave similar results to the un-restricted model, which suggests that the propensity score was able to sufficiently balance differences in the distribution of covariates between the treatment and control groups.

Outcomes for combined estrogen/progestin methods were compared with progestin-only methods using a sample of 601 women with 55.7% right censoring. Combined hormonal users had hazard ratio of 1.79 in the crude analysis. After adjustment with propensity score weighting, the hazard for combined users was 2.90 (95% CI 2.30, 3.66).

DISCUSSION

Use of combined estrogen/progestin contraception was strongly associated with breastfeeding duration in our study. The adjusted hazard ratios for use of a combined hormonal method compared to no method, non-hormonal methods, or progestin-only methods ranged from 2.76 to 3.07 (Table 23). These results strongly support earlier findings from studies carried out in other countries. Because of the cultural and social influences on breastfeeding, it is important for policy and program implementation to test the association in a current US population to ensure that results seen elsewhere and in previous eras have the same association given the current context for breastfeeding in the US. This study also addresses contraceptive methods and formulations currently available in the US. Furthermore, this study adds strength to earlier findings by controlling for many potential confounders not addressed in much of the earlier literature.

Bivariate analyses, showed significant differences between women who used combined estrogen/progestin forms of contraception and those who used progestin-only, non-hormonal methods or no contraception. Breastfeeding women who used a hormonal form of contraception after birth were significantly younger than mothers who used a

non-hormonal method or chose not to use contraception, which could reflect maternal preference, but could also be the result of age differences in clinician recommendation.

Highly effective forms of non-hormonal birth control, like the copper IUD, were traditionally not recommended for younger women, and older mothers may be advised against hormonal methods, which are contraindicated with age. Age differences in access to healthcare, could also lead to differences in the options available to women of different age groups. Alternatively, clinicians may assume that preventing future pregnancies is more important to younger mothers and suggest hormonal methods in an attempt to give these women reliable control over their fertility. Since younger mothers also have shorter duration of breastfeeding than older mothers, use of combined estrogen/progestin methods could be contributing to this difference in health outcome.

Differences in contraceptive use by race/ethnicity were identified in the bivariate analysis, but were not pronounced for use of combined estrogen/progestin methods. White mothers were the most likely to use this form of contraception (14.4%), followed closely by blacks (12.8%) and Hispanics (11.4%). Therefore, use of combined hormonal methods is unlikely to explain the differences in breastfeeding outcomes by race.

Mothers with a high school or college degree were more likely to use combined estrogen/progestin birth control than those with either more or less education. It is somewhat surprisingly that mothers without a high school degree would have a better health behavior than their more educated peers. Education may be a proxy for Socio-economic status in this sample, in which case, less educated mothers may be more likely to be receiving their care from public health programs. This would suggest that these programs are more successfully guiding breastfeeding mothers to breastfeeding

compatible contraception or making these options more available or more appealing than is being done in other segments of the healthcare system. If so, these public health systems could serve a model for shifting postpartum contraceptive use in other settings.

Primiparous mothers used combined hormonal methods almost twice as often as multiparous mothers. Given the magnitude of effect shown here, this difference could explain an important portion of the effect of parity on breastfeeding outcomes, and has implications for clinical care. Given the high use of combined estrogen/progestin contraception in the US, first-time mothers may simply be returning to methods of contraception with which they are most familiar. They may also be less aware than more experienced mothers that these methods are not recommended while breastfeeding. If so, these mothers may need more information and counseling on contraception, and standard of care should be adjusted to provide extra time during postpartum obstetric appointments for first time mothers so that this can take place.

Another place where trends in breastfeeding outcomes may be at least partially explained by the use of combined hormonal contraception is the longer breastfeeding durations for female infants observed in some studies. In this sample, mothers of male infants used combined hormonal methods 15.3% of the time but only 11.8% of the time for female infants. It's unclear why this would be the case or why mothers would nurse their female baby's longer, but the sizes of these effects are similar.

Women who had not intended to breastfeed before birth, but did initiate breastfeeding were the most likely sub-population to use combined estrogen/progestin methods (22.6%). However, only 2.4% of mothers in this sample fell into this category. The higher use of contraceptive methods that are not recommended during breastfeeding

could represent a lack of commitment to breastfeeding by these women, or it could be explained by ignorance of breastfeeding-related issues among women who did not think these topics were relevant to them prior to birth. Since these women are a breastfeeding success story, further attention should be paid to whether their use of contraceptive methods that are contraindicated for breastfeeding represents an intentional choice on their part or ignorance of potential contraindications. Policy, therefore, might include targeted continued postpartum counseling on both breastfeeding and contraception for this population.

Confounding is a particular problem in this area of work since the differences exist between the groups of women using each type of contraception. Women who breastfeed are also different on a variety of characteristics from those who do not breastfeed. Ethical and human subjects issues make many study designs meant to address this problem, such as performing an RCT, impractical. Therefore, other approaches are needed to address confounding. Results from this study suggest that propensity score weighting may be a useful method in this field. Propensity score weights were used to balance the characteristics of the exposure and control groups as a means of controlling for the differences in these populations. Histograms of the propensity score weights used in the survival analysis showed considerable overlap between treatment groups, suggesting that the propensity score successfully balanced the distribution of their characteristics. However, there were some areas with representation from only one group or the other. An analysis of the area of common support gave consistent results to the more general hazard model, suggesting that this technique adequately matched the treatment and control groups. If successfully matched, propensity scores allow one to

217

assess the counterfactual scenario where everyone in the sample received the treatment or everyone received the control. This is useful and appropriate for the topic of postpartum contraception since contraceptive use is a changeable factor. Knowing the population effect, therefore, could be informative for policy and program design and have implications for clinical practice.

LIMITATIONS

An important limitation of this study is the lack of information about the timing of initial contraceptive use. Estrogen, too, has been shown to impact lactation; in humans it is considered a potent inhibitor of milk production based on clinical reports. (91-95) Biological models suggest that early introduction of progestogenic contraception after birth may disrupt breastfeeding establishment, while later introduction may have no effect or a supportive effect on breastfeeding outcomes. If this is the case, this study would not be able to distinguish these effects since all women who used progestin-containing methods were grouped together, regardless of early or late onset of use. The available data did not allow evaluation of the intensity or exclusivity of breastfeeding, and therefore assessment of more nuanced breastfeeding outcomes could not be carried out. Examination of these important indicators of breastfeeding success would help to clarify the true effects of contraception on breastfeeding.

The high amount of censored data in this sample (69.0%) may limit the power to detect differences in breastfeeding duration between contraceptive use groups. While their ultimate duration of breastfeeding is unavailable for these women, it is informative

that they were able to breastfeed as long as they reported, and that this occurred in the context of their reported contraceptive use. Moreover, this would likely be a less significant issue at earlier time-points, which is the time frame of most interest since women may be a more vulnerable to breastfeeding cessation as the biology and behavior of breastfeeding are being established. Censoring could bias the sample if it was associated with the outcomes, breastfeeding or contraceptive use. This sample was selected at random from birth certificate data, limiting this possibility; however, if availability by landline telephone or willingness to participate in a telephone survey was correlated with breastfeeding outcomes or contraceptive use this could introduce bias.

This analysis is also vulnerable to the possibility that women began using contraception after breastfeeding cessation. However, most women in this sample were still breastfeeding, and their achieved duration was accomplished in the context of their contraceptive use or non-use. Moreover, the infants in this sample were relatively young, which further limits this possibility of reverse causation.

Intensity or exclusivity of breastfeeding could not be evaluated in this sample, and therefore could not assess these more nuanced breastfeeding outcomes. This is unfortunate, since exclusivity is a relevant outcome of interest in relation to milk supply, a potential point of impact for exogenous hormones like those in hormonal contraception.

In the United States, there is a large drop-off in breastfeeding rates during the first year, which could affect the ability of this study to detect associations between contraceptive use and breastfeeding outcomes. If factors such as social, demographic, and healthcare are more important to breastfeeding cessation than biological factors, it may be difficult to detect the biological impact of contraceptive use if there is residual

confounding. Unmeasured factors that contribute to breastfeeding cessation could be wrongly attributed in this study as an effect of contraceptive use. The use of propensity scores is intended to address the multi-faceted nature of this topic area and, therefore, address this concern.

Confounding is a particular problem in this area of work as seen by the significant demographic differences between the users of different types of postpartum contraception. Similarly, there were significant demographic differences between those who did and did not initiate breastfeeding and by duration (reported for this sample in chapter 2). However, propensity score weighting was able to adequately balance the demographic characteristics of women in the different contraceptive use categories. This suggests that this technique may be useful in controlling for confounding and examining causality in future studies on contraceptive use while breastfeeding.

A limitation of propensity scores is the assumption of no unmeasured confounders. Breastfeeding and contraceptive use both have complex etiologies that include social, psychological, biological, and healthcare factors. This dataset is unusual in the breastfeeding literature for the number and quality of breastfeeding and contraception related questions it asks. However, information on timing and sequencing of contraceptive use, partnership status, social support for breastfeeding, maternal depression, urbanicity, and maternal obesity, and others were not available in this dataset. To the extent that the factors available are more proximal to the outcome, they may serve as adequate proxies for these and other unmeasured factors and mitigate the vulnerability of using this statistical approach. Furthermore, it should be noted that the assumption of

no unmeasured confounders is also present for other common statistical approaches, and therefore not specific to this analytic design.

The sample population was selected from North Carolina Birth Certificates and contacted by telephone. Differences in the covariates and in contraceptive use may exist between those available by landline telephone and those who cannot be reached by this means including those who do not have a landline telephone. For instance, people who use cell phones exclusively would not be available by this means, and this could disproportionately exclude younger, poorer, and more transient mothers from the sample leading to sample bias. If willingness to participate in a telephone survey were not randomly distributed, the sample would also be biased. These concerns are addressed in two ways. First, the random selection process using birth certificate records provides an unbiased foundation for sample selection. In addition, many measures were undertaken to contact potential subjects including multiple contact attempts, contact at different times of the day and week, and contact attempts over several months. Furthermore, if the potential participant declined, efforts were made by specially trained personnel to convince the potential study subjects to participate.

The retrospective study design relied on maternal self-report and is vulnerable to recall bias which would be more likely to affect transient factors and factors with perceived positive or negative connotation. For example, unwanted and mistimed pregnancies are reported less often in this sample than has been found in national data. Mothers may be reluctant to tell the interviewer that their pregnancy was unwanted or mistimed, and she might also unconsciously re-evaluate the wantedness of her pregnancy as she begins to bond with her baby. Similarly, a mother's recall of her intention to

breastfeed may change in light of her actual experience of breastfeeding. Reporting of hospital practices may be also be bias by events that happen later, and mothers could simply not remember what occurred during that time. Some may not even know whether and when events happened, which could be correlated with maternal or infant health. Finally, reporting of contraceptive use may be subject to recall bias, especially if more than one method has been used since birth. This sample is likely comparable to other studies in the field of breastfeeding research since results from this study are consistent with other breastfeeding studies on covariates commonly reported in the literature.

Non-random missing data could lead to sample bias, however the amount of missing data for the variables used in the model was 1%-3%, which is very low. Few factors in the model were significantly associated with contraceptive use suggesting that this model was missing variables that influence the use of contraception after birth. For instance, partnership status, whether the mother is sexually active, and whether she has achieved her desired family size could all be important factors in using contraception, but were not available in the dataset. Timing of contraceptive use would also have been useful to provide a more complete description of postpartum contraception. This is particularly true for women who reported using more than one method since birth because the timing, order and duration of these methods were unknown. However, the sample is unusual in that is has information about breastfeeding outcomes alongside information about contraceptive use, enabling analysis of contraception use during breastfeeding. Few analyses of postpartum contraceptive use have been carried out in adult populations, so this study also contributes to the literature by describing factors associated with contraceptive use in this large and meaningful demographic.

CONCLUSION

Combined estrogen/progestin contraceptive methods had a large effect on breastfeeding duration when compared to progestin-only methods, non-hormonal methods or using no method. These results suggest that combined hormonal methods should not be recommended to breastfeeding women. This is consistent with current CDC recommendations and strengthens the evidence on which they're founded because this study was recent and US-based, examined current contraceptive options, and controlled for confounding using up-to-date statistical approaches. The use of propensity scores in our survival analysis successfully matched our study groups, and impacted the estimation of effect, particularly for comparison with non-hormonal and progestin-only methods. Propensity scores may be a useful technique for future work in the field. This is particularly compelling given the differences identified between women who use different types of contraception after birth.

Table 19: Characteristics of the Population From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11 (N=1,319).		
	Total	**Percentage of Total**
	N=1,319	100%
Maternal Age (years)		
Mean	30.3	
Median	31	
Race/Ethnicity		
Non-Hispanic White	876	66.4%

Non-Hispanic Black	133	10.1%
Hispanic	273	20.7%
Other	37	2.8%
Maternal Education		
Less than High School	157	11.9%
High School	345	26.2%
College	536	40.6%
Graduate School	281	21.3%
Pregnancy Wantedness		
Wanted at This Time	816	61.9%
Not Wanted / Mistimed	330	25.0%
All Pregnancies Wanted	173	13.1%
First Child		
Yes	475	36.0%
No	844	64.0%
Baby's Gender		
Female	684	51.9%
Male	635	48.1%
NICU Stay		
no	1,171	88.8%
yes	148	11.2%
Intention to Breastfeed		
No	31	2.4%
Yes	1,288	97.6%
Timing of Initiation		
< 1 Hour	584	44.3%
1 to <2 Hours	265	20.1%
2 to 24 Hours	336	25.5%
> 24 Hours	134	10.1%

Table 20: Breastfeeding Status by Month Among Women Who Initiated Breastfeeding From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11. (N=1,319).

	Not Breastfeeding n (%)	Breastfeeding n (%)
1 Month	169 (12.8%)	1,150 (87.2%)
2 Months	336 (25.5%)	983 (74.5%)
3 Months	589 (44.7%)	730 (55.3%)
4 months	1,017 (77.1%)	302 (22.9%)
5 Months	1,298 (98.4%)	21 (1.6%)
> =6 Months	1,310 (99.3%)	9 (6.8%)
Received Formula Sample Bag		
No	311	23.6%
Yes	1,008	76.4%
Hospital Practices		
Mean	3.9	3.9
Median	4	4

Table 21a: Characteristics of the Population (continuous variables) by Method of Postpartum Contraceptive Use (N=1,319). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11 and Limited to Women Who Initiated Breastfeeding.

	No Method	Non-Hormonal	Progestin-Only	Combined Estrogen / Progestin	Total
	323 (24.5%)	395 (29.9%)	423 (32.1%)	178 (13.5%)	1,319 (100%)
Maternal Age* (years)**					

Mean	31.8	31.5	28.9	28.5	30.3
Median	32	32	30	29	31
Infant Age at interview (months)					
Mean	3.28	3.23	3.26	3.49	3.29
Median	3	3	3	3	3
Infant Age					
No	83 (26.7%)	87 (28.0%)	108 (34.7%)	33 (10.6%)	311
Yes	240 (23.8%)	308 (30.6%)	315 (31.3%)	145 (14.4%)	1,008
Hospital Practices					
Mean	3.9	3.8	3.9	4.0	3.9
Median	4	4	4	4	4
*** p<0.001					

Table 21b: Characteristics of the Population by Method of Postpartum Contraceptive Use (N=1,319). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11 and Limited to Women Who Initiated Breastfeeding.

	No Method n (%)	Non-Hormonal n (%)	Progestin-Only n (%)	Combined Estrogen / Progestin n (%)	Total n (%)
	323 (24.5%)	395 (29.9%)	423 (32.1%)	178 (13.5%)	1,319 (100%)
Race/Ethnicity**					
Non-Hispanic White	224 (25.6%)	254 (29.0%)	272 (31.1%)	126 (14.4%)	876
Non-Hispanic Black	36 (27.1%)	25 (18.8%)	55 (41.4%)	17 (12.8%)	133
Hispanic	54	101	87	31	273

	(19.8%)	(37.0%)	(31.9%)	(11.4%)	
Other	9 (24.3%)	15 (40.5%)	9 (24.3%)	4 (10.8%)	37
Maternal Education*					
Less than High School	28 (17.8%)	58 (36.9%)	52 (33.1%)	19 (12.1%)	157
High School	70 (20.3%)	101 (29.3%)	118 (34.2%)	56 (16.2%)	345
College	146 (27.2%)	148 (27.6%)	167 (31.2%)	75 (14.0%)	536
Graduate School	79 (28.1%)	88 (31.3%)	86 (30.6%)	28 (10.0%)	281
Pregnancy Wantedness					
Wanted at This Time	210 (25.7%)	241 (29.5%)	256 (31.4%)	109 (13.4%)	816
Not Wanted / Mistimed	64 (19.4%)	99 (30.0%)	121 (36.7%)	46 (13.9%)	330
All Pregnancies Wanted	49 (28.3%)	55 (31.8%)	46 (26.6%)	23 (13.3%)	173
First Child***					
Yes	108 (22.7%)	106 (22.3%)	171 (36.0%)	90 (19.0%)	475
No	215 (25.5%)	289 (34.2%)	252 (29.9%)	88 (10.4%)	844
Baby's Gender					
Female	171 (25.0%)	202 (29.5%)	230 (33.6%)	81 (11.8%)	684
Male	152 (23.9%)	193 (30.4%)	193 (30.4%)	97 (15.3%)	635
NICU Stay					
no	290 (24.8%)	357 (30.5%)	367 (31.3%)	157 (13.4%)	1,171

yes	33 (22.3%)	38 (25.7%)	56 (37.8%)	21 (14.2%)	148
Intention to Breastfeed					
No	8 (25.8%)	5 (16.1%)	11 (35.5%)	7 (22.6%)	31
Yes	315 (24.5%)	390 (30.3%)	412 (32.0%)	171 (13.3%)	1,288
Timing of Initiation					
< 1 Hour	162 (27.7%)	172 (29.5%)	184 (31.5%)	66 (11.3%)	584
1 to <2 Hours	53 (20.0%)	84 (31.7%)	88 (33.2%)	40 (15.1%)	265
2 to 24 Hours	77 (22.9%)	94 (28.0%)	110 (32.7%)	55 (16.4%)	336
> 24 Hours	31 (23.1%)	45 (33.6%)	41 (30.6%)	17 (12.7%)	134
Received Formula Sample Bag					
No	83 (26.7%)	87 (28.0%)	108 (34.7%)	33 (10.6%)	311
Yes	240 (23.8%)	308 (30.6%)	315 (31.3%)	145 (14.4%)	1,008
***** **p<0.001 ** p<0.01 * p<0.05**					

Table 22: Association of Lactation Support Visit in Hospital with Contraceptive Method Use (N=1,319). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11, and Limited to Women Who Initiated Breastfeeding.

	No Method n (%)	Non-Hormonal n (%)	Progestin-only n (%)	Combined Estrogen / Progestin n (%)	Total n (%)
Visit*†					

228

No	56 (23.1%)	89(36.6%)	75(30.9%)	23(9.5%)	243 (18.4%)
Yes	267(24.8%)	306(28.4%)	348(32.3%)	155(14.4%)	1,076 (81.6%)
Total	323	395	423	178	1,319 (100%)

* p<0.05
† This variable is included in the ordinal "Hospital Practices" variable and is not included as a separate variable in the analyses.

Table 23: Hazard of Breastfeeding Cessation as a Function of Type of Contraceptive Used (N=1,319). Sample Drawn From a Survey Evaluating the Period of Purple Crying Intervention Program, 2010-11 and Limited to Women Who Initiated Breastfeeding.

	Hazard Ratio	Lower 95% CL	Upper 95% CL	Likelihood ratio test	Sample Size	Percent censored
Combined estrogen/progestin	referent					
No Method	3.07	2.39	3.96	p<.0001	499	54,6%
Non-hormonal methods	2.76	2.19	3.49	p<.0001	574	55.6%
Progestin-only methods	2.90	2.30	3.66	p<.0001	600	55.9%

*Adjusted for maternal age, race/ethnicity, maternal education, pregnancy wantedness, parity, baby's gender, NICU stay, intention to breastfeed, timing of initiation, receipt of a formula sample bag, and hospital practices through the propensity score.

Figure 7: Survival Plots of Breastfeeding Duration by Type of Contraception Used.
From a Survey Evaluating the Period of Purple Crying intervention program, 2010-11, and limited to women who initiated breastfeeding. Curves are adjusted for maternal age, race/ethnicity, maternal education, pregnancy wantedness, parity, baby's gender, NICU stay, intention to breastfeed, timing of initiation, receipt of a formula sample bag, and hospital practices through propensity score weights.

Combined Estrogen/Progestin vs. Progestin-only Methods

% Still Breastfeeding

Breastfeeding Duration (weeks)

Contraceptive Type: —— Progestin-only Methods
- - Combined Estrogen/Progestin
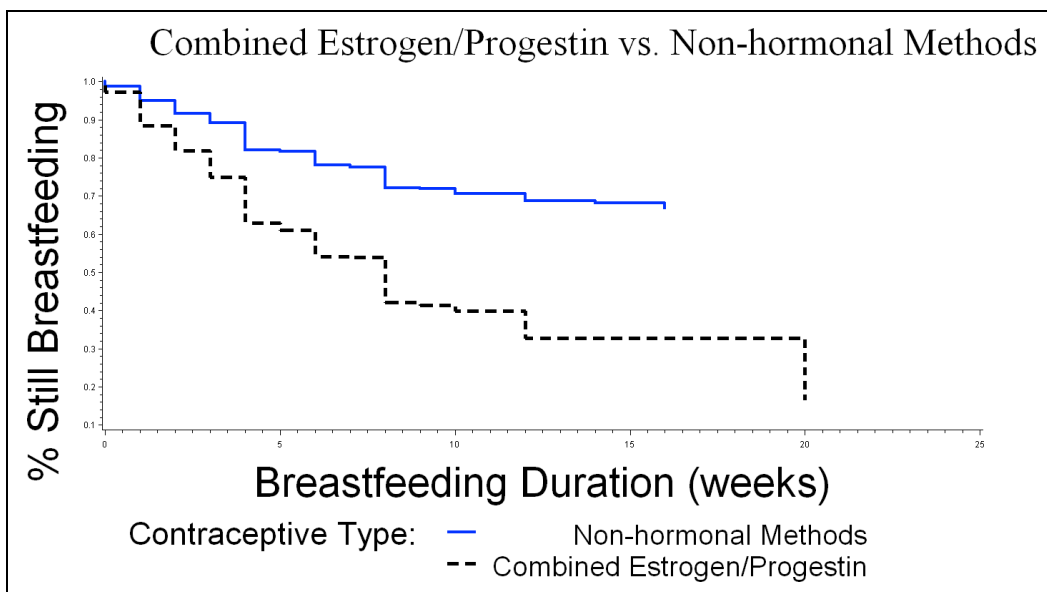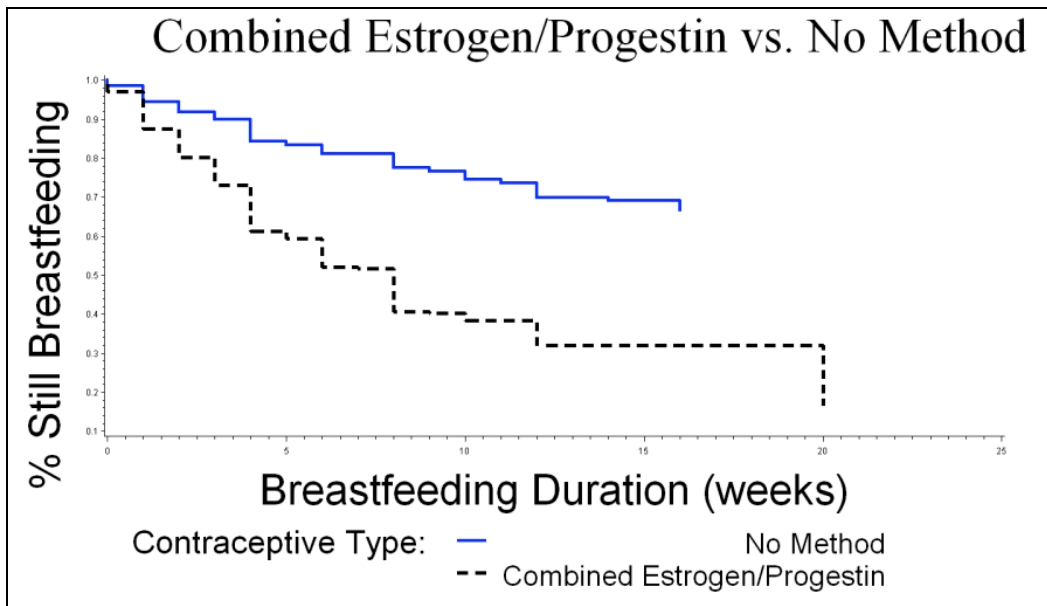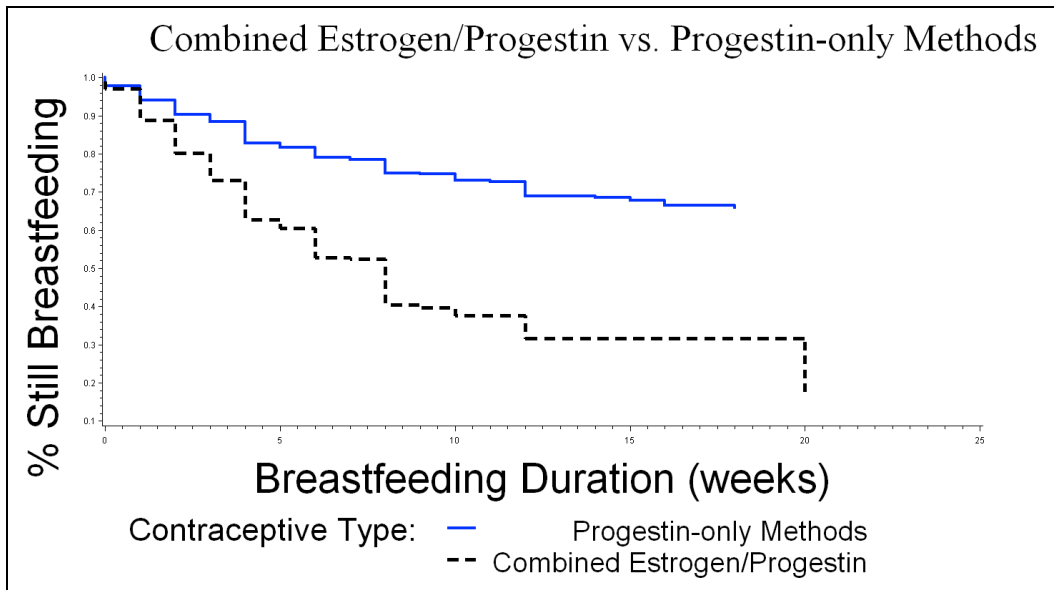
CHAPTER VI: CONCLUSION

The purpose of this project was to examine the breastfeeding and contraceptive use patterns of a US-based population to inform policy, programs, and clinical care around breastfeeding and contraceptive use in the postpartum timeframe. The public health importance of both breastfeeding and family planning are widely acknowledged as individual issues, but where they come together, there has been controversy. US and international sources give contradictory recommendations, and within the US, care-providers from different branches of the medical community disagree about what they witness in their patient populations. Much of the scientific literature available to inform this conversation has significant limitations in its generalizability to the US today. Many of these studies were carried out over twenty years ago, and as a result, the contraceptive methods studied are, in many cases, not available today in the same dose or form. The statistical methods used, while standard for their era, are often not up to date with current practices and in many instances fail to properly control for issues now known to be associated with either breastfeeding or contraceptive use. Perhaps most fundamentally, the settings for these studies may not be generalizable to the US in 2013. Many were carried out in countries that have a very different cultural norm around breastfeeding, sexuality, relationships, and women's roles in society. This is accentuated by the age of the studies and the global changes that have taken place in recent decades including introduction of computers, cell phones, and the internet, as well as, economic

globalization, all of which have changed the social context for breastfeeding and family planning considerably. The context for breastfeeding in these studies may have been more conducive to the biological feedback system that establishes and maintains milk supply. This could have made women in these settings less susceptible to the effects of hormonal contraception than women who breastfeed with less biologically conductive patterns, such as many women in the US today. This study aimed to contribute to this important public health topic by contributing up to date information from a setting within the US using statistical methods suited to the complexity of the subject area.

The study was carried out in 2010 and 2011 across North Carolina, an advantageous laboratory for breastfeeding research. North Carolina falls in the middle of the US spectrum of states in terms of breastfeeding outcomes. It has a diversity of urban and rural areas and significant immigration from other parts of the country, providing a mixture of social norms from other regions of the country. The state has been influenced on the local, state, and national level by both political parties, which has implications for breastfeeding-related laws and policies as well as the social climate. There is also a sizable minority of African Americans and Hispanics, allowing examination of racial and ethnic differences and issues of health disparity. Together, this makes North Carolina a useful setting to explore the current state of breastfeeding in the US, and well suited to addresses public health questions of national interest.

Hormonal Contraceptive Use

Combined estrogen/progestin contraception was negatively associated with breastfeeding duration in this study, and the magnitude of the effect after adjusting for

233

confounding ranged from 2.76 to 3.07 in comparisons with no method, non-hormonal

methods, or progestin-only methods. These results add up-to-date and culturally specific

evidence to support the current CDC recommendations against use of combined

hormonal contraception while breastfeeding. This study also updates the literature in

regards to current contraceptive options and through use of more-advanced statistical

methods to control for confounding. Use of propensity score weighting enables

estimation of a population effect, which makes it clear that the impact on breastfeeding

duration would be large if these methods were more widely used.

Progestin-only methods of contraception had no statistically significant

association with breastfeeding duration in this study. Clinical reports suggest that early

postpartum use of progestin-only methods may adversely affect breastfeeding outcomes,

however, the most recent updates to the CDC medical eligibility criteria, which were

released in June 2013 specifically clarify that progestin-only methods are considered

compatible with breastfeeding beginning immediately after birth. Non-significant trends

in the adjusted model of time to breastfeeding cessation are consistent with previous

literature on late-onset use of progestin-only contraception that shows either no effect or

longer breastfeeding duration with use of these methods. However, this analysis lacked

sufficient information on the timing of contraceptive use to resolve the controversy since

early and late use of these methods could not be differentiated. Consequently, these

results should not be interpreted to mean that progestin-only methods are compatible with

breastfeeding, but rather that good information about the timing of use will be necessary

to clarify the relationship between progestin-only contraceptive use and breastfeeding

outcomes.

Differences in the distribution of demographic, psychosocial, health and healthcare characteristics of those who use particular types of contraception after birth follow similar patterns to breastfeeding outcomes, suggesting that the two issues may be interrelated. A better understanding of these trends is necessary to inform development and implementation of policies and programs to improve health outcomes associated with breastfeeding and family planning, and to guide best practices in clinical care.

Maternal age

Maternal age was found to be significantly associated with initiation of breastfeeding, as reported elsewhere. Older mothers were more likely to begin breastfeeding than their younger counterparts. Similarly, breastfeeding women who used a hormonal form of contraception after birth were significantly younger than mothers who used a non-hormonal method or chose not to use contraception. In light of the association between use of combined hormonal contraceptive methods and shorter breastfeeding duration identified in this study, contraceptive use may be a factor in the shorter breastfeeding duration for younger mothers, which is reported elsewhere and suggested by non-significant trends in this data. Differences in contraceptive use by age could reflect maternal choice; younger mothers may have a preference for hormonal contraception perhaps because they are more familiar with it than other methods. Age differences may reflect women returning to methods they used before pregnancy, since younger women tend to use hormonal contraception in higher proportions than older women. Estrogenic hormonal contraception is contra-indicated with age, which could mean that older mothers are avoiding hormonal methods as the risk of side-effects

increases. These trends could also be related to a decline in sexual activity with age or a difference in how young and old mothers prioritize pregnancy prevention relative to breastfeeding protection. Older mothers in this study were more likely to not be using contraception, indicating that pregnancy prevention may play a smaller role in their decision making than for younger mothers. To the extent that maternal preference drives this trend, results of this study suggest that younger mothers in particular may need better counseling after birth in order to make decisions about contraception that are compatible with their breastfeeding plans. Education about highly effective non-hormonal contraceptive options, such as the copper IUD, may be particularly important for younger mothers who may be less likely to know about or have tried these methods previously.

Differences in clinical care may also be a factor in age-related contraceptive trends. Access to healthcare, could lead to differences in the contraceptive options available to women by age. For instance, the out of pocket cost of contraception may affect younger mothers disproportionately if their financial means or health insurance coverage is lower. If so, this adds further justification for healthcare policy to ensure realistic access to contraception for all mothers. On the other hand, clinicians may assume that preventing future pregnancies is more important to younger women or they may have a personal bias towards pregnancy prevention for younger mothers. As a result, they may suggest hormonal methods in an attempt to give these women reliable control over their fertility. To the extent that age-related patterns are clinician-driven, better clinician education is called for so that they have the necessary knowledge and motivation to help mothers balance pregnancy prevention and breastfeeding protection. All of these explanations highlight a need to fully understand the association between the

236

type of contraceptive used while breastfeeding and breastfeeding outcomes to ensure that contraceptive use is not contributing to the age-related disparity in breastfeeding outcomes.

Race/Ethnicity

Racial and ethnic differences in breastfeeding outcomes in this study are consistent with national trends. Hispanics have the highest initiation and continuation rates, followed by whites and then blacks, whose initiation rate lags whites by nearly twenty percentage points. This striking racial health behavior difference may be a foundation for other health disparities for blacks since breastfeeding is associated with a range of better health outcomes. In terms of breastfeeding, race is likely a proxy for a variety of socioeconomic and cultural factors that define distinct contexts for breastfeeding for different racial/ethnic groups. To improve breastfeeding outcomes for black mothers, identifying and addressing the barriers to breastfeeding specific to this group will be important. In the analysis of breastfeeding duration for the sub-population of women who successfully initiate breastfeeding, no significant difference between black and white mothers was identified. This suggests that breastfeeding initiation is a critical moment in which to address the lower breastfeeding rates among blacks, and that once over this hurdle, their breastfeeding outcomes are similar to those of whites. Efforts to improve the health disparity in breastfeeding rates for blacks should be targeted at breastfeeding initiation.

Hispanic mothers may be a model for breastfeeding promotion; identifying the factors associated with their higher rates of initiation and continuation could provide

237

insight into improving outcomes for white and black mothers. One factor on which they differ is postpartum contraceptive use. Race/ethnicity was one of only two factors associated with the use of combined estrogen/progestin methods after birth. White mothers were the most likely to use this form of contraception, and were much more likely to do so than Hispanic mothers. Given the magnitude of effect identified for use of combined hormonal contraception, the difference in use of this method may explain some of the racial/ethnic differences in breastfeeding duration. Thus the cultural and behavioral decision could have a biological consequence through breastfeeding.

Race/ethnicity was also a strong predictor of progestin-only use. Black women had a much higher risk of using a progestin-only method compared to both white and Hispanic mothers. Overall, black mothers had the highest use of hormonal contraceptives in this population, with over half of black mothers using one of these methods. This study was not able to rule out the possibility that early use of progestin-only methods is negatively associated with breastfeeding outcomes. If clinical reports suggesting this are true, contraceptive use patterns of black mothers may contribute to the health disparity in breastfeeding outcomes for black mother-baby dyads. Contraceptive use patterns of Hispanic mothers would be consistent with this possibility. Hispanic mothers have the highest rate of breastfeeding, and although they are the group with the highest use of postpartum contraception, with over 80% using birth control, they use non-hormonal methods much more often than either white or black mothers.

The high rate of contraceptive use among Hispanics suggests that pregnancy prevention may be a more important to factor for Hispanic mothers after birth than for white and black mothers. This could be due to a greater desire to prevent pregnancy on

the part of Hispanic mothers themselves, but it could also reflect racial bias from healthcare providers or differences in access to contraception based on cost or type of health insurance. While Hispanic mothers have the best breastfeeding outcomes of the racial/ethnic groups evaluated in this study, their continuation rate still lags behind national goals. Over 10% of Hispanic mothers who initiated breastfeeding were none-the-less using combined hormonal methods of contraception. Given the tendency to use birth control in the postpartum period, extra contraceptive counseling may be needed by Hispanic mothers to achieve national targets on breastfeeding duration.

Education

Breastfeeding duration was nearly identical for mothers with high school degrees and those who had not completed high school, but for higher levels of education, there seemed to be a dose-response effect on breastfeeding duration. Similar to the results for race, the difference in breastfeeding duration between college educated mothers and those with less education disappeared in the analysis that included only those who had initiated breastfeeding, implying that the positive association with being college educated primarily affects breastfeeding initiation. Women with a graduate degree, however, continued to have a significantly lower risk of breastfeeding cessation even after accounting for differences in initiation. Maternal educational is often considered a proxy for socioeconomic status; however, in this instance it may be capturing additional dimensions relevant for breastfeeding outcomes. Other possible explanations for the dose-response could be increased knowledge of breastfeeding, maternal self-efficacy, differences in partnership dynamics, economic power within the family, and differences

239

in decision-making responsibility, amongst other possible explanations. Alternatively, highly educated women may be more likely to have work environments that are conducive for breastfeeding, have access to maternity leave, or be able to choose not to work. Identifying the factors that contribute to the better outcomes of these mothers could inform policies and programs to help meet the national breastfeeding continuation goals for women of all educational levels.

One area in which more educated mothers differ from their less educated peers is contraceptive use. Women with college and graduate degrees were at higher risk of using a progestin-only method when compared to women with less than a high school education. This may indicate that more educated mothers are more likely to follow the CDC recommendations than less educated mothers. To the extent that women are relying on these guidelines to make choices in contraceptive use, these results underscore the importance of resolving the controversy around progestin-only methods.

Mothers with a high school education or less were more likely to use contraception after birth than college and graduate school educated mothers. This may reflect differences in socio-economic status and the perceived impact of another pregnancy. Pregnancy prevention may be more important to less educated mothers, but bias from healthcare providers could also play a role, either consciously or unconsciously assuming that more children would be undesirable for less educated women. Our findings suggest that identifying and promoting effective birth control that is compatible with breastfeeding is an important factor in improving the disparity in breastfeeding continuation between more and less educated mothers.

Cost and health insurance factors may also play a role in which method a woman uses, which could affect less educated mothers disproportionately. Legislation ensuring access to affordable health insurance and mandating coverage for birth control may improve access to contraception for all mothers, but especially for those who currently fall between public and high quality private insurance options. Evidence that this "donut-hole" effect may apply to postpartum contraception was found in the patterns of use of combined estrogen/progestin methods. Mothers with the lowest educational attainment, less than high school, and mothers with the highest, graduate degrees, were both less likely to use combined hormonal methods than women in the middle of the educational spectrum, high school and college graduates. This may reflect different factors. Highly educated mothers may be better informed or more concerned about the negative association between use of these methods and breastfeeding outcomes, whereas access to care and cost may drive contraceptive use by less educated mothers compared to women in the middle of the educational spectrum. If education is a proxy for SES in this sample, less educated mothers may be more likely to receive their care from public health programs. If so, this suggests that these programs are more successfully guiding breastfeeding mothers to breastfeeding-compatible contraception or making these options more available or more appealing than is being done in other segments of the healthcare system. To the extent that this is true, these public health systems could serve a model for shifting postpartum contraceptive use in other settings.

Pregnancy Wantedness

Mothers with timely, wanted pregnancies were more likely to begin breastfeeding than those with unwanted/mistimed pregnancies or for whom all pregnancies would be wanted. Amongst women who initiated breastfeeding, pregnancy wantedness was significantly associated with duration. This factor, not generally included in the US-based studies, suggests that control over her fertility may affect the health and parenting choices women make after birth. Effective and available contraception, then, becomes a generational issue, conferring life-long health disparities on the children of women who do not have access to or choose not to use it. Improving breastfeeding outcomes for these mother-baby dyads could help break this cycle. These mothers may need additional breastfeeding support and clinicians involved in both prenatal and postnatal care should be educated about the association between wantedness and breastfeeding outcomes. Furthermore, pregnancy wantedness could be used as a marker to identify mothers for programs encouraging breastfeeding initiation and continuation.

In this sample, pregnancy wantedness was not significantly associated with the type of contraceptive used after that birth. However, this study may have underestimated the association between pregnancy wantedness and contraceptive use because many fewer women in this population reported unwanted or untimely pregnancies compared to national statistics. Trends in the data suggest that this topic might merit future research. The higher rate of contraceptive use among those with an unwanted or mistimed pregnancy suggests that a woman's attitude about her pregnancy may affect her preference for using birth control in the postpartum period. Given the association with shorter duration of breastfeeding identified in this study, contraceptive use may explain

some of the differences in breastfeeding outcomes identified for women with unwanted/mistimed pregnancies. These findings suggest that breastfeeding outcomes can be influenced by pre-conception factors, and that the interrelatedness of family planning and breastfeeding exists even before a woman has conceived her first child. The effects of family planning, then, extend to breastfeeding outcomes and health consequences, and further highlight the importance of universal access to available and effective birth control to address disparities and improve public health.

Infant Gender

Another place where trends in breastfeeding outcomes may be at least partially explained by contraceptive use is the somewhat surprising observation reported in some studies that female infants are breastfed for longer than male infants. In this sample, mothers of male infants used combined hormonal contraceptive methods 15.3% of the time compared with 11.8% for mothers of female infants. Given the magnitude of effect identified for use of these methods, the association with shorter breastfeeding intervals could be related to this difference in contraceptive use. Male infants tend to have greater health issues than female, and improving breastfeeding outcomes for these babies may improve their health since breastfeeding is associated with a variety of better infant health outcomes. More research is needed to understand why differences in maternal contraceptive use would be related to infant gender, but decreasing the use of combined estrogen/progestin contraception by mothers of boys may be a surprising, but fruitful avenue for improving gender-based differences in infant health.

Parity

First-time mothers had higher odds of breastfeeding cessation relative to mothers with older biological children. First-time motherhood was also one of only two characteristics significantly associated with use of combined estrogen/progestin contraception in this population. The strong association between use of these methods and shorter breastfeeding duration identified in this study may explain some of the difference in breastfeeding outcomes between these groups. Social factors and experience are sometimes thought to underlie the disparity between primiparous and multiparous mothers. However, if contraceptive use were contributing to differences in their duration of breastfeeding, it would provide a far more tractable opportunity to improve breastfeeding outcomes for primiparous mothers.

Evidence for a social effect is found also in this study. An interaction term showing a composite effect for NICU stay and parity shows a lower risk of breastfeeding cessation among first time mothers whose baby spends time in the NICU. This is somewhat counter-intuitive since the infants in these mother-baby dyads are less healthy than their peers. Since the improved breastfeeding outcomes are unlikely to be attributable to infant factors, this suggests that, for first-time mothers, interaction with the NICU is beneficial for breastfeeding. Thus, NICUs may be a model for healthcare practices that promote breastfeeding for first-time mothers.

NICU

Mothers whose babies have been in the NICU are at significantly higher risk of using a progestin-only method compared to non-hormonal contraception. These women

may perceive a greater need for birth control because of the separation from their child or because they are not able to fully breastfeed their baby. Changes in the standard of care at many NICUs now often encourage mothers to breastfeed, so these mothers may be more aware of the CDC recommendations for contraceptive use while breastfeeding. NICU stay was not significantly associated with breastfeeding initiation or duration in this study, suggesting that the health and other challenges associated with having a baby in the NICU, which have the potential to negatively affect breastfeeding, are being successfully managed in this regard. Information about breastfeeding exclusivity was not available in this dataset and it may be that breastfeeding exclusivity is lower for NICU mothers than the general population. Even so, these results suggest that practices carried out in the NICU may be a useful model for breastfeeding-supportive care in other parts of the healthcare system, with special attention paid to the measures NICU units have taken to improve their breastfeeding rates.

Intention to Breastfeed

Intention to breastfeed was highly associated with both initiation and duration of breastfeeding. The magnitude of this association suggests that influencing women's breastfeeding intention may be a high-yield opportunity for improving breastfeeding outcomes. Some studies note that women make decisions about breastfeeding prior to or early in their pregnancies, which would point to a need for health education campaigns aimed at women and their families before conception or early in prenatal care, instead of towards the end of their pregnancies as is common in many prenatal care settings.

About 5.5% of women who intended to breastfeed did not initiate; this may have been due to adverse experiences during or immediately following labor and delivery, such as maternal or infant illness, hospital practices or other events that interfered with initiation. On the other hand, 15.9% of women who had not planned to breastfeed none-the-less initiated breastfeeding. From a breastfeeding advocacy standpoint, these women represent a possible success for the institutions where this conversion from non-breastfeeders to breastfeeders occurs since they are likely either permissive or encouraging of this shift. Moreover, these changes from original intention suggest that experiences around birth can affect breastfeeding outcomes away from what the mother intended. A higher percentage of women were converted from non-breastfeeders to breastfeeders than the other direction, and this may indicate that activities ongoing in NC hospital settings may be reflected in breastfeeding support. This hypothesis is supported by the fact that those who initiated breastfeeding reported more of the Ten-Step hospital practices that are known to be associated with breastfeeding initiation in other settings. (199)

Women who had not intended to breastfeed before birth, but did initiate breastfeeding were the most likely sub-population in this study to use combined estrogen/progestin methods. The higher use of contraceptive methods associated with shorter breastfeeding duration could represent a lack of commitment to breastfeeding by these women, or it could be explained by ignorance of breastfeeding-related issues among women who did not think these topics were relevant to them prior to birth. Since these women are a breastfeeding success story, further attention should be paid to whether their use of methods that are contraindicated for breastfeeding represents an

intentional choice on their part or ignorance of potential challenges. Policy, therefore, might include targeted continued postpartum counseling on both breastfeeding and contraception for this population.

Hospital Practices

The Ten Steps to Successful Breastfeeding guidelines were developed by UNICEF and WHO to provide guidance for clinicians providing obstetric and maternity care regarding practices that support a mothers' ability to succeed in breastfeeding initiation and achieve longer durations of breastfeeding. Seven of these steps related to maternity care practices around birth and the immediate postpartum time frame. Women who received a formula sample bag, part of Step 6, were less likely to initiate breastfeeding than those who did not receive a sample bag. Because initiation comes before the sample bag would be offered, this could reflect a lack of system-wide support for breastfeeding. This study confirmed that receipt of formula sample bags is associated with shorter breastfeeding duration. Having formula on-hand may provide an easy "solution" during breastfeeding challenges, and creates a path to feeding supplements, which can disrupt the physiology of milk supply and lead to weaning. Another explanation for this association may be that formula sample bags could be a proxy for a number of other, unmeasured practices and interactions that either discourage breastfeeding or pre-dispose it to be of shorter duration, as suggested by the association with breastfeeding initiation. In North Carolina, the setting for this study, efforts by the North Carolina Breastfeeding Coalition (NCBC) to encourage hospitals not to provide these bags in North Carolina have resulted in hospitals eliminating formula sample bags

247

as a first step, and this may or may not be the only, clearly defined change to breastfeeding-related maternity practices. (210) Thus, stopping provision of formula sample bags may be an early marker that a hospital is moving towards more breastfeeding friendly policies.

Initiation of breastfeeding within the first hour after birth, as per Step 4 of the Ten Steps, is significantly associated with breastfeeding duration. Relative to early initiation, all later time points, including initiation between the first and second hours, were associated with significantly shorter duration of breastfeeding, and none of these later times of initiation were significantly different from each other. This supports the concept that there may be a critical window for breastfeeding initiation and further supports the contention that hospital policies for delivery practices may have a long-term impact on breastfeeding.

The five other hospital practices evaluated in this study were immediate skin-to-skin contact after birth, infant rooming-in, visit by a lactation consultant or other breastfeeding support person, observation of a feeding by a lactation consultant or other breastfeeding support person, and whether the mother felt supported in her feeding choice by all facility staff. The mean number of practices reported by women who initiated breastfeeding was 3.9, in contrast to only 2.5 for women who did not begin nursing. Individually, all five practices were also significantly associated with breastfeeding initiation, confirming that the maternity care practices endorsed in the Ten Steps are positively associated with this measure of breastfeeding success. While there was a trend towards positive associations with breastfeeding duration, this association was not statistically significant. This could indicate that other factors have a bigger impact on

longer-term breastfeeding outcomes. Recall bias or confusion with the survey questions could also be an issue. Nonetheless, all seven of the Ten Step hospital practices evaluated in this study were found to have a significant association with breastfeeding outcomes, adding evidence that these measures are relevant and worthwhile for breastfeeding promotion in the current US maternity care setting. This has important implications for public health policy and for best practices for clinical care. This work further substantiates that implementation of the Ten Step guidelines could improve breastfeeding outcomes in the US and should be strongly considered by policy-makers.

The number of breastfeeding-supportive maternity practices experienced by the mother was associated with use of a progestin-only method compared to non-hormonal methods; however the effect was only marginally significant and should be taken with caution. Women who receive the standard of care for maternity practices, however, may also be more likely to receive the standard of care, i.e. follow the CDC guidelines, in regards to contraceptive use. However, this result could also represent confounding by other factors that are associated with both contraceptive use and hospital care, such as health insurance or size or type of hospital at which the woman gave birth. Likewise, examination of the individual practices that comprised the ordinal 'Hospital Practices' variable, revealed a significant association between a visit by an LC or breastfeeding support person and the type of contraceptive used. It could be that women experiencing breastfeeding difficulties are both more likely to receive an LC visit and more likely to contracept, but since non-hormonal methods are considered by breastfeeding advocates to be the more conservative choice for breastfeeding preservation, these results, like the findings for hospital practices in general are surprising. Again, given that the CDC

recommendations do not prioritize non-hormonal methods over progestin-only methods while breastfeeding; these results may indicate that women are being effectively educated about the current guidelines before initiating contraceptive use and that they are following those guidelines. This further underscores the importance of gathering accurate information about the association between exposure to progestins while breastfeeding and the need to translate this work into evidence based guidelines for contraceptive use during lactation.

An interaction term between maternal age and the number of hospital practices reported by the mother shows a protective effect that increases with both maternal age and the number of breastfeeding supportive hospital practices a woman receives. This result should be interpreted with caution since it is only marginally significant at the $p<0.05$ level. On the other hand, both maternal age and hospital practices have been associated with increased duration of breastfeeding in other studies, so it is plausible that these factors could play a role in breastfeeding success. While the odds ratio appears to be small, just 1.3% lower odds per maternal year and hospital practice, the impact can quickly add up when one considers maternal ages of 20, 30 or 40 years, and multiple hospital practices. The implication of this term, if valid, is that hospital practices affect older mothers differently than younger ones. Further research is needed to clarify whether this effect is spurious, but to the extent that it reflects real differences among mothers, it has important implications for the implementation of breastfeeding-related hospital practices and for improving health disparities between mothers of different ages.

Statistical Methods

The physiology of breastfeeding should be equally unaffected by no contraceptive use and by using a non-hormonal method. However the results of this study suggest that caution should be used in selecting the best comparison group for future research on contraceptive use while breastfeeding because the adjusted survival curves and bivariate analyses using different comparison groups show different trends. To the extent that the use or non-use of contraception defines distinct populations of women, those who choose not to use contraception may not be the most appropriate comparison group for the effects of hormonal contraceptive methods. Women who do not use contraception after birth may represent a very different population than those who use contraception in this period, and therefore utilizing them as a comparison group may not fully control for factors that are not otherwise captured in the model but are associated with contraceptive use. For instance, studies that utilize non-users as the control group may not be adequately controlling for partnership status, which has been shown to be positively associated with breastfeeding outcomes. (156,158,160) Much of the literature on which the WHO and CDC MECs are based, however, make use of those who are not using contraception as their control group. Many of these studies report no effect of hormonal methods, particularly progestin-only methods, but the results of this analysis suggest that use of an inadequate control group may be contributing to these results. This may be particularly true if the effect being studied is more subtle or time varying, as is hypothesized for progestin-only methods, since even relatively small mismatches in populations may obscure more subtle associations.

Confounding is a particular problem in this area of work since differences exist between the groups of women using each type of contraception. Women who breastfeed also differ from those who do not breastfeed on a variety of characteristics. Ethical and human subjects issues make many study designs meant to address this problem, such as performing an RCT, impractical. Therefore, other approaches are needed to address confounding. Results from this study suggest that propensity score weighting may be a useful method in this field. Propensity score weights were used to balance the characteristics of the exposure and control groups as a means of controlling for the differences in these populations. Histograms of the propensity score weights used in the survival analysis showed considerable overlap between treatment groups, suggesting that the propensity score successfully balanced the distribution of their characteristics. An analysis of the area of common support gave consistent results to the more general hazard models, reinforcing that the propensity scores adequately matched the treatment and control groups. If successfully matched, propensity scores allow one to assess the counterfactual scenario where everyone in the sample received the treatment or everyone received the control. This is useful and appropriate for the topic of postpartum contraception since contraceptive use is a changeable factor. Knowing the population effect, therefore, could be informative for policy and program design and have practical implications for clinical practice.

Theory of Planned Behavior

This project confirmed the predictions of the Theory of Planned Behavior. The mother's intention to breastfeed was strongly associated with breastfeeding duration both

including and excluding initiation. Moreover, all seven hospital practices evaluated in

this study were significantly associated with breastfeeding initiation, bearing out the

prediction of the theory that underlying factors that affect one's subjective norm, and

one's perceived behavioral control can work through behavioral intention to lead to

behavior. Specifically, in this study, 15.9% of women who did not intend to breastfeed, in

fact, did initiate. According to the Theory of planned Behavior, the care they received at

the hospital could have shifted these women's subjective norm and perceived behavioral

control enabling them to deviate from their intention and carry out a behavior they had

not previously planned to take-up. While many other influences may impact this shift,

hospital practices offer an opportunity for policy and programmatic intervention that

directly impacts the time period and setting where the decision to breastfeed is made.

Future work should continue to be informed by this theory since it has shown good

relevance and insight for this subject matter.

LIMITATIONS

An important limitation of this study is the lack of information about the timing of

initial contraceptive use. Estrogen has been shown to impact lactation; in humans it is

considered a potent inhibitor of milk production based on clinical reports. (91-95)

Biological models suggest that early introduction of progestogenic contraception after

birth may disrupt breastfeeding establishment, while later introduction may have no

effect or a supportive effect on breastfeeding outcomes. If this is the case, this study

would not be able to distinguish these effects since all women who used progestin-

containing methods were grouped together, regardless of early or late onset of use. The available data did not allow evaluation of the intensity or exclusivity of breastfeeding, and therefore assessment of more nuanced breastfeeding outcomes could not be carried out. Examination of these important indicators of breastfeeding success would help to clarify the effects of progestin-only contraception on breastfeeding and the true effects of hormonal contraception in general.

The high amount of censored data in this sample (69.0%) may limit the power to detect differences in breastfeeding duration between contraceptive use groups. While their ultimate duration of breastfeeding is unavailable for these women, it is informative that they were able to breastfeed as long as they reported, and that this occurred in the context of their reported contraceptive use. Moreover, censoring would likely be a less significant issue at earlier time-points, which is the time frame of most interest since women may be a more vulnerable to breastfeeding cessation as the biology and behavior of breastfeeding are being established. This is also the time frame in which progestin-only methods are hypothesized to have the greatest impact. Censoring could bias the sample if it was associated with the outcomes, breastfeeding or contraceptive use. This sample was selected at random from birth certificate data, limiting this possibility; however, if availability by landline telephone or willingness to participate in a telephone survey was correlated with breastfeeding outcomes or contraceptive use this could introduce bias.

This analysis is also vulnerable to the possibility that women began using contraception after breastfeeding cessation. However, most women in this sample were still breastfeeding, and their achieved duration was accomplished in the context of their

contraceptive use or non-use. Moreover, the infants in this sample were relatively young, which further limits this possibility of reverse causation.

Intensity or exclusivity of breastfeeding could not be evaluated in this sample, and therefore could not assess these more nuanced breastfeeding outcomes. This is unfortunate, since exclusivity is a relevant outcome of interest in relation to milk supply, a potential point of impact for exogenous hormones like those in hormonal contraception.

In the United States, there is a large drop-off in breastfeeding rates during the first year, which could affect the ability of this study to detect associations between contraceptive use and breastfeeding outcomes. If factors such as social, demographic, and healthcare are more important to breastfeeding cessation than biological factors, it may be difficult to detect the biological impact of contraceptive use if there is residual confounding. Unmeasured factors that contribute to breastfeeding cessation could be wrongly attributed in this study as an effect of contraceptive use. The use of propensity scores is intended to address the multi-faceted nature of this topic area and, therefore, address this concern.

Confounding is a particular problem in this area of work as seen by the significant demographic differences between the users of different types of postpartum contraception. Similarly, there were significant demographic differences between those who did and did not initiate breastfeeding and by duration (reported for this sample in chapter 2). However, propensity score weighting was able to adequately balance the demographic characteristics of women in the different contraceptive use categories. This suggests that this technique may be useful in controlling for confounding and examining causality in future studies on contraceptive use while breastfeeding.

255

A limitation of propensity scores is the assumption of no unmeasured confounders. Breastfeeding and contraceptive use both have complex etiologies that include social, psychological, biological, and healthcare factors. This dataset is unusual in the breastfeeding literature for the number and quality of breastfeeding and contraception related questions it asks. However, information on timing and sequencing of contraceptive use, partnership status, social support for breastfeeding, maternal depression, urbanicity, and maternal obesity, employment and others were not available in this dataset. To the extent that the factors available are more proximal to the outcome, they may serve as adequate proxies for these and other unmeasured factors and mitigate the vulnerability of using this statistical approach. Furthermore, it should be noted that the assumption of no unmeasured confounders is also present for other common statistical approaches, and therefore not specific to this analytic design.

The sample population was selected from North Carolina Birth Certificates and contacted by telephone. Differences in the covariates and in contraceptive use may exist between those available by landline telephone and those who cannot be reached by this means including those who do not have a landline telephone. For instance, people who use cell phones exclusively would not be available by this means, and this could disproportionately exclude younger, poorer, and more transient mothers from the sample leading to sample bias. If willingness to participate in a telephone survey were not randomly distributed, the sample would also be biased. These concerns are addressed in two ways. First, the random selection process using birth certificate records provides an unbiased foundation for sample selection. In addition, many measures were undertaken to contact potential subjects including multiple contact attempts, contact at different times

of the day and week, and contact attempts over several months. Furthermore, if the potential participant declined, efforts were made by specially trained personnel to convince the potential study subjects to participate.

The retrospective study design relied on maternal self-report and is vulnerable to recall bias which would be more likely to affect transient factors and factors with perceived positive or negative connotation. For example, unwanted and mistimed pregnancies are reported less often in this sample than has been found in national data. Mothers may be reluctant to tell the interviewer that their pregnancy was unwanted or mistimed, and she might also unconsciously re-evaluate the wantedness of her pregnancy as she begins to bond with her baby. Similarly, a mother's recall of her intention to breastfeed may change in light of her actual experience of breastfeeding. Reporting of hospital practices may be also be bias by events that happen later, and mothers could simply not remember what occurred during that time. Some may not even know whether and when events happened, which could be correlated with maternal or infant health. Finally, reporting of contraceptive use may be subject to recall bias, especially if more than one method has been used since birth. This sample is likely comparable to other studies in the field of breastfeeding research since results from this study are consistent with other breastfeeding studies on covariates commonly reported in the literature.

Non-random missing data could lead to sample bias; however the amount of missing data for the variables used in the model was 1%-3%, which is very low. Few factors in the model were significantly associated with contraceptive use suggesting that this model was missing variables that influence the use of contraception after birth. For instance, partnership status, whether the mother is sexually active, and whether she has

achieved her desired family size could all be important factors in using contraception, but were not available in the dataset. Timing of contraceptive use would also have been useful to provide a more complete description of postpartum contraception. This is particularly true for women who reported using more than one method since birth because the timing, order and duration of these methods were unknown. However, the sample is unusual in that is has information about breastfeeding outcomes alongside information about contraceptive use, enabling analysis of contraception use during breastfeeding. Few analyses of postpartum contraceptive use have been carried out in adult populations, so this study also contributes to the literature by describing factors associated with contraceptive use in this large and meaningful demographic.

CONCLUSION

Combined estrogen/progestin contraceptive methods had a large effect on breastfeeding duration when compared to progestin-only methods, non-hormonal methods or using no method. These results suggest that combined hormonal methods should not be recommended to breastfeeding women. This is consistent with current CDC recommendations and strengthens the evidence on which they're founded because this study is recent, US-based, examined current contraceptive options, and controlled for confounding using up-to-date statistical approaches. No effect of progestin-only contraceptive use on breastfeeding duration was found when compared to either non-hormonal methods of birth control or using no method. These results are limited by the lack of information on the timing of initiation of use; in particular, we were not able to

258

distinguish early use, i.e., immediate postpartum, from later use. Consequently, these results should not be interpreted to mean that progestin-only methods are compatible with breastfeeding, but rather that good information about the timing of use will be necessary to clarify the relationship between progestin-only contraceptive use and breastfeeding outcomes.

Postpartum contraceptive use by women who initiated breastfeeding was found to be associated with maternal age, maternal educational attainment, race/ethnicity, first birth, infant NICU stay, and the number of breastfeeding-related hospital practices experienced by the mother. Differences in contraception use correspond to breastfeeding rates, suggesting that the issues may be related either with common etiology or by direct effects between them. Pregnancy prevention may outweigh breastfeeding protection in a mother's use of contraception after birth. If so, accurate and available information about the impact of hormonal contraception on breastfeeding is need by these women, as well as having access to reliable and attractive contraceptive methods which are compatible with breastfeeding.

Overall, these results highlight the importance of labor and delivery practices that allow and enable immediate breastfeeding initiation for long-term breastfeeding success. These results support the importance of the Ten Steps to Successful Breastfeeding for breastfeeding duration, and suggest that greater adoption of and adherence to this standard could improve breastfeeding outcomes.

APPENDIX 1: HISTOGRAMS OF THE PROPENSITY SCORE WEIGHTS FOR TREATMENT AND CONTROL GROUPS FOR EACH SURVIVAL ANALYSIS

From a Survey Evaluating the Period of purple crying intervention program, 2010-11, and limited to women who initiated breastfeeding. Propensity scores are based on maternal age, race/ethnicity, maternal education, pregnancy wantedness, parity, baby's gender, NICU stay, intention to breastfeed, timing of initiation, receipt of a formula sample bag, and hospital practices.

Progestin-Only vs. No Method

Propensity Score Weights
0= No method
1= Progestin-only Methods
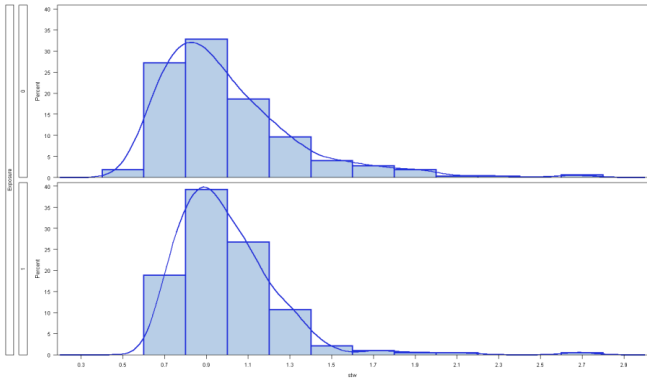
Progestin-Only vs. Non-hormonal Methods

Propensity Score Weights
0= Non-hormonal methods
1= Progestin-only Methods

260
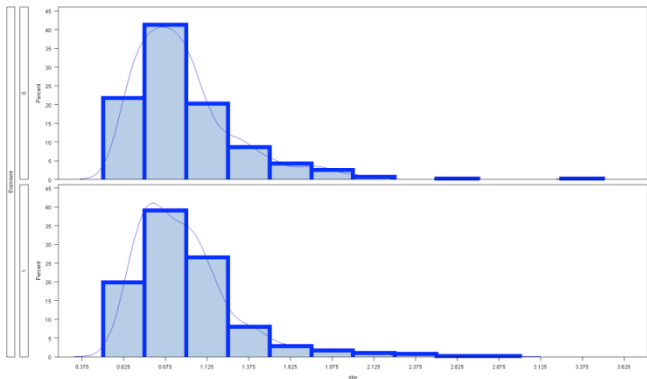
APPENDIX 2: HISTOGRAMS OF THE PROPENSITY SCORE WEIGHTS FOR TREATMENT AND CONTROL GROUPS FOR EACH SURVIVAL ANALYSIS

From a Survey Evaluating the Period of Purple Crying intervention program, 2010-11, and limited to women who initiated breastfeeding. Propensity scores are based on maternal age, race/ethnicity, maternal education, pregnancy wantedness, parity, baby's gender, NICU stay, intention to breastfeed, timing of initiation, receipt of a formula sample bag, and hospital practices.

Combined Hormonal vs. No Method

Propensity Score Weights
0= no method
1= combined hormonal
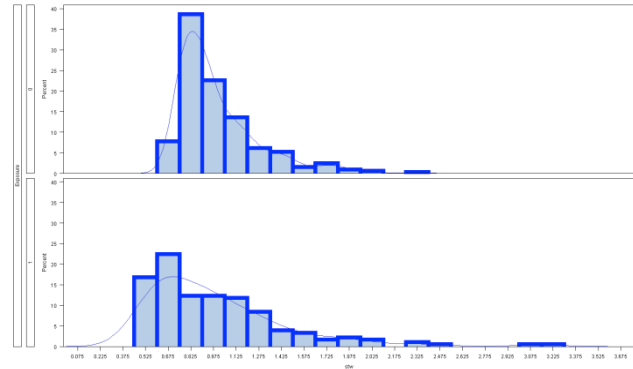
Combined Hormonal vs. Non-hormonal Methods

Propensity Score Weights
0= non-hormonal methods
1= combined hormonal
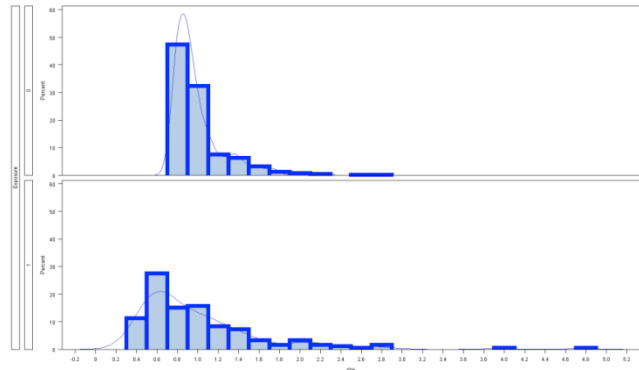
Combined Hormonal vs. Progestin-Only Methods

Propensity Score Weights
0= progestin-only
1= combined hormonal

Study	Year and Location	Study Design	Exposure	Population	Results	Study problems	Reference
Peralta et al	1983 Chile	Partially randomized controlled trial	30 days PP: N=103 EE 0.03 mg and LNG 0.15 mg; N=109 received injectable placebo at 30 days; N=79 used oral placebo	N=291 healthy women, exclusively breastfeeding at day 30-35 postpartum.	At 3 months, COC users had significantly lower rates of exclusive breastfeeding (80.6% vs. 92%). At 6-8 months, 16-33% of COC users had weaned, versus 9-19% of non-hormonal users and 5-17% of IUD users. Average infant weight was lower in the COC group than controls	Participants chose their treatment / control status. The COC group had higher parity than the controls.	Diaz S, Peralta O, Juez G, Herreros C, Casado ME, Salvatierra AM, et al. Fertility regulation in nursing women: III. Short-term influence of a low-dose combined oral contraceptive upon lactation and infant growth. Contraception 1983 Jan;27(1):1-11.

							Croxatto HB, Diaz S, Peralta O, Juez G, Herreros C, Casado ME, et al. Fertility regulation in nursing women: IV. Long-term influence of a low-dose combined oral contraceptive initiated at day 30 postpartum upon lactation and infant growth. Contraception 1983 Jan;27(1):13-25.
Croxatto et al	1983 Chile	Partially randomized controlled trial	30 days PP: N=103 EEl 0.03 mg and LNG 0.15 mg; N=188 received injectable placebo at 30 days and non-hormonal contraceptive at 90 days PP; N=118 used non-hormonal IUD	N=330 healthy, exclusively breastfeeding women.	From 4 to 10 months, COC group had significantly lower exclusive breastfeeding rates than both control groups. For most months, COC group had lower average infant weight than controls.	Participants chose their treatment/control status. The COC group had higher parity than the controls.	
Kaern	1967 Copenhagen, Denmark	RCT	Trial window was 1 to 8 days PP: N=233 received daily Norinyl-1	N=451 healthy postpartum women who planned to	At discharge (day 8), 11.2% of Treatment and 3.2% of controls were giving supplemental feeding.	Duration of follow-up was very short, randomizati	Kaern T. Effect of an oral contraceptive

			tablet (norethisterone 1 mg and mestranol 0.05 mg); N=218 received placebo	breastfeed		on and blinding process are unclear, statistical findings don't match their conclusions	immediately post partum on initiation of lactation. Br Med J 1967 Sep 9;3(5566):644-645.
Miller and Hughes	1970, USA	RCT	Intervention began at 2 weeks postpartum N=24 received 1mg norethindrone with 0.08 mg mestranol N=23 received placebo until 6 weeks and then COCs N=48 no treatment	N=100 women who planned to breastfeed for at least 3 months	Breastfeeding continuation at 12 weeks: 21% of COC treatment group, 52% of placebo/COC group, 73% of controls. At weeks 4 and 5, babies of nonusers had significantly higher weight gain. Week 5 COC users' babies needed more supplemental calories.	Study failed to specify randomization methods, statistical tests, and values of results	Miller GH, Hughes LR. Lactation and genital involution effects of a new low-dose oral contraceptive on breast-feeding mothers and their infants. Obstet Gynecol 1970 Jan;35(1):44-50.

WHO	Hungary and Thailand	RCT	Treatment began at 6 weeks PP N=86 COC (30 µg ethinyl estradiol and 150 µg levonorgestrel) N=85 POP (75 µg norgestrel) N=59 DMPA N=111 Non-hormonal (barriers, sterilization, IUDs)	N=341 healthy women aged 20-35 who wanted oral contraceptives. Had to have 2-5 previous births and prior successful breastfeeding experience of at least 3 months	No differences found in breastfeeding continuation rates, mean infant weight, length, or rate of growth, or infant illness were found between COC and control groups, except female infants at one site were smaller in controls than COC group. Milk from COC group was lower in calories, and had different mineral content, and milk volume was lower than controls.	No adjustment for confounders. Loss to follow-up was high in some groups. Supplementation not addressed. Method switching not addressed.	WHO. Effects of hormonal contraceptives on breast milk composition and infant growth. World Health Organization (WHO) Task Force on Oral Contraceptives. Stud Fam Plann 1988 Nov-Dec;19(6 Pt 1):361-369.
Guiloff et al	1974, Chile	randomized clinical trial/ case-only design with historical controls	N=367 various regimens of COC; N=80 DMPA; N=168 POP; N=81 IUD (COC and IUD users began at 30 days postpartum; DMPA users began at 1-2	n=696 16-40-year-old healthy, multiparous women	Median duration of lactation (MDL) was shorter for COC users. No significant difference in MDL for the group given an EE formulation (4.6 vs. 5.3 for non-hormonal controls). Metrenol and quingestanol users had a significant (p<0.05) difference in MDL (2.5 vs. 5.3)	Control group was the previous births from the same women. No further accounting for confounding.	Guiloff E, Ibarra-Polo A, Zanartu J, Toscanini C, Mischler TW, Gomez-Rogers C. Effect of contraception on lactation.

			days postpartum)				Am J Obstet Gynecol 1974 Jan 1;118(1):42-45.
Gambrell	1968-69 US Military Hospital, Wiesbade, Germany	Prospective Cohort	Treatment started on PP day 5: N=363 received COC of the type they had previously used or randomly selected from 9 available options (83 breastfeeding) N=245 Controls (91 breastfeeding)	N=964 immediately postpartum women who wanted oral contraception	Among breastfeeding women, 54% of the COC group and 59% of the control group breastfed for 6 or more weeks. The reason for breastfeeding cessation was due to decreased milk supply for 25% of the COC group and 13% of the controls	No adjustment for confounders. variety of COCs grouped together in treatment group. Intervention was self-selected. Time of breastfeeding initiation appears to vary.	Gambrell RD,Jr. Immediate postpartum oral contraception. Obstet Gynecol 1970 Jul;36(1):101-106.
Nilsson et al	1979 Sweden	Retrospective Cohort	N=48 women who used COCs while breastfeeding N=48 Non-hormonal users	N=96 women who asked for COCs at 2 months postpartum and their matched	Mean length of breastfeeding was shorter in the COC group than controls (3.7 vs. 4.6) , but no differences in number of serious illness or school performance were found were found up to age 8	No adjustment for confounders. Retrospective design. Small	Nilsson S, Mellbin T, Hofvander Y, Sundelin C, Valentin J, Nygren KG. Long-term

				controls		numbers.	follow-up of children breast-fed by mothers using oral contraceptives. Contraception 1986 Nov;34(5): 443-457.
Peralta et al	1983 Chile	Prospective cohort	treatment began at 90 days postpartum: N=59 EE 0.03 mg and LNG 0.15 mg; N=82 received non-hormonal method	N=141 healthy, exclusively breastfeeding women whose infants had normal weight gain at 3 months	At 6 months, COC group had significantly lower exclusive breastfeeding rates than non-hormonal. At 4 months, COC group had lower infant weight gain than non-hormonal	No adjustment for confounders, and COC group had higher parity than the controls. participants chose their treatment/control status	Peralta O, Diaz S, Juez G, Herreros C, Casado ME, Salvatierra AM, et al. Fertility regulation in nursing women: V. Long-term influence of a low-dose combined oral contraceptive initiated at day 90 postpartum upon

							lactation and infant growth. Contraception 1983 Jan;27(1):27-38.

Injectables: DMPA & NET-EN

Study	Year and Location	Study Design	Exposure	Population	Results	Study problems	Reference
Guiloff et al	1974 Chile	randomized clinical trial/ case-only design with historical controls	Randomized to receive DMPA immediately PP (N=80) or at 1 month PP (N=33)	N=696 16 to 40 year-old multiparous women	Median duration of breastfeeding for immediate postpartum use was 6.7 months vs. shot at 1-month was 4.8 month breastfeeding duration; women who received a shot at 1 month breastfed longer than the control, group (9.3 vs. 5.3 months)	Control group was the previous births from the same women. No further accounting for confounding.	Guiloff E, Ibarra-Polo A, Zanartu J, Toscanini C, Mischler TW, Gomez-Rogers C. Effect of contraception on lactation. Am J Obstet Gynecol 1974 Jan 1;118(1):42-45.
Hannon et al	1997 Baltimore, MD	prospective cohort study	At time of hospital discharge: N=45 DMPA(150 mg); N=52	N=95, intended to breastfeed and were breastfeeding at hospital	No significant difference between early postpartum use of medroxyprogesterone and use of non-hormonal methods but trend towards	Statistically significant differences in age and marital status between the	Hannon PR, Duggan AK, Serwint JR,

			non-hormonal	discharge	longer breastfeeding duration in treatment group (10.14 weeks for DMPA vs. 6.57 weeks for non-hormonal, P=.19)	exposure groups were not addressed in the analysis, not controlling for these possible confounders at all.	Vogelhut JW, Witter F, DeAngelis C. The influence of medroxyprogesterone on the duration of breast-feeding in mothers in an urban community. Arch Pediatr Adolesc Med 1997 May;151(5):490-496.
Halderman and Nelson	2002 Los Angeles, CA	Prospective cohort	women self-selected to receive DMPA before discharge (N=102), receive a prescription for POPs or LNG	N=319 women of all ages, parity, and prior breastfeeding experience	Women using hormonal contraception were significantly more likely to have ceased breastfeeding at 4 weeks (83.1% for non-hormonal, 76.7% for POCs, p=0.022), but no difference was found at 2 and 6 weeks.	No adjustment for confounding. Groups were significantly different in their prior breastfeeding experience, mother's age, and mode of	Halderman LD, Nelson AL. Impact of early postpartum administration of progestin-only

			implant (N=77) or use condoms or abstinence (N=138)			delivery.	hormonal contraceptives compared with non-hormonal contraceptives on short-term breast-feeding patterns. Am J Obstet Gynecol 2002 Jun;186(6):1250-6; discussion 1256-8.
Lawrie et al	(1998) South Africa	RCT	48 hours PP: N=85 received NET-EN; N=84 received placebo	N=166 breastfeeding women, over 19 years old	Breastfeeding continuation rates were 68% for NET-EN group and 74% for placebo, but not statistically significant at 6 or 12 weeks postpartum. No differences in infant weight	Small sample size might have been underpowered to see effect.	Lawrie TA, Hofmeyr GJ, De Jager M, Berk M, Paiker J, Viljoen E. A double blind randomized placebo-controlled

272

							trial of postnatal norethisterone enanthate: the effect on postnatal depression and serum hormones. Br J Obstet Gynaecol 1998 Oct;105(10):1082-1090.
Brito et al	(2009) Brazil	RCT	N= received ETG implant 24-48 hours PP N= received 150 mg DMPA, 6 weeks PP	N=40 women with chronic disease, BMI<30, aged 18-35 years, no history of thromboembolism	At 12 weeks PP, no difference between implant and DMPA groups in exclusive breastfeeding rates (17/20 ETG, 15/20 DMPA), no differences in infant weight observed.	Comparison of one treatment to another treatment, combines time and treatment such that the two effects cannot be differentiated. Does not inform about either treatment relative to	Brito MB, Ferriani RA, Quintana SM, Yazlle ME, Silva de Sa MF, Vieira CS. Safety of the etonogestrel-releasing implant during the immediate

					biological norm. Follow-up only to 12 weeks.		postpartum period: a pilot study. Contraception 2009 Dec;80(6): 519-526.
Karim et al.	1969 Egypt	Prospective Cohort	7 days PP: N=80 DMPA; N=68 Net-EN (200 mg every 84 days); N=51 DMPA (150 mg every 3 months); N=100 Non-hormonal. 42 days PP: N=57 NET-EN; N=55 DMPA.	N=331 women with normal delivery	No difference in milk chemistry, volume, or infant growth was observed. Women reported similar or longer duration breastfeeding compared to previous nursing experiences.	Duration of breastfeeding was anecdotal.	Karim M, Ammar R, el-Mahgoub S, el-Ganzoury B, Fikri F, Abdou I. Injected progestogen and lactation. Br Med J 1971 Jan 23;1(5742):200-203.
Jimenez et al.	(1984) Chile	Retrospective Cohort	2 months PP: N=128 DMPA (150 mg/3 months); N=142 non-hormonal	N=270 women who breastfed	DMPA mothers reported longer breastfeeding duration, 21 months vs. 13 for controls. No difference in child development measures or health measures. No difference in child weight after adjustment for confounders.	Retrospective design could lead to recall bias for breastfeeding outcomes. Exposure not randomized.	Jimenez J, Ochoa M, Soler MP, Portales P. Long-term follow-up of children breast-fed by mothers receiving

							depot-medroxyprogesterone acetate. Contraception 1984 Dec;30(6): 523-533.
Melis et al.	(1981) Italy	Observational Cohort	N=5 NET-EN to puerperal women on 2-5 day PP; N=20 NET-EN to non-puerperal women on 5th day of menses	N=25 women	No effect on breastfeeding reported.	small sample size, no control for breastfeeding outcomes	Melis GB, Strigini F, Fruzzetti F, Paoletti AM, Rainer E, Dusterberg B, et al. Norethisterone enanthate as an injectable contraceptive in puerperal and non-puerperal women. Contraception 1981 Jan;23(1):77-88.

Shaaban et al.	(1991) Egypt	Cohort	5-7 weeks PP: N=120 LNG implant (Norplant); N=120 NET-EN injectable; N=120 IUD inserted in 2nd month PP; N=103 PVR; N=83 Copper IUD.	Phase I: N=360 healthy women. Phase II: N=186 women	Phase I: No difference in supplementation timing. IUD users ceased breastfeeding earlier than NET-EN users. No difference in infant outcomes. Phase II: No difference in supplementation or infant growth between Vaginal ring and IUD users.	Poor reporting of baseline characteristics, follow-up, and methods.	Shaaban MM. Contraception with progestogens and progesterone during lactation. J Steroid Biochem Mol Biol 1991;40(4-6):705-710.
Zacharias et al.	(1986) Chile	Prospective Cohort	2 to 4 months PP: N=143 LAM; N=109 IUD; N=228 DMPA; N=185 POP (Clogestone Acetate .6 mg/day)	N=665 term women who were willing to breastfeed	Median breastfeeding duration was 17 months for LAM and 19 months for IUD, DMPA, and POP combined. DMPA had the highest percentage of mothers nursing past 20 months.	Subjects self-selected treatment and no adjustment for confounders.	Zacharias S, Aguilera E, Assenzo JR, Zanartu J. Effects of hormonal and nonhormonal contraceptives on lactation and incidence of pregnancy. Contracept

| WHO | (1994) Egypt, Iran, Thailand, Kenya, Chile, Hungary | Cohort | 6-8 weeks PP: N=475 POP (LNG or lynestrenol); N=541 DMPA; N-121 NET-EN; N=453 LNG implant (Norplant); N=876 non-hormonal | N=2466 married women with term deliveries. | No difference in frequency and duration of breastfeeding between contraceptive types at the same site, but differences seen between locations. Infant growth and development outcomes were inconsistent between sites. | Breastfeeding outcomes varied greatly between sites. | ion 1986 Mar;33(3): 203-213.

Progestogen-only contraceptives during lactation: I. Infant growth. World Health Organization Task force for Epidemiological Research on Reproductive Health; Special Programme of Research, Development and Research Training in Human Reproducti |

							on. Contraception 1994 Jul;50(1):35-53. Progestogen-only contraceptives during lactation: II. Infant development. World Health Organization, Task Force for Epidemiological Research on Reproductive Health; Special Programme of Research, Development, and Research Training in Human Reproducti

							on. Contraception 1994 Jul;50(1):55-68.
WHO	Hungary and Thailand	RCT	6 weeks PP: N=86 COC (30 µg EE and 150 µg LNG N=85 POP (75 µg norgestrel) N=59 DMPA N=111 Non-hormonal (barriers, sterilization, IUDs)	N=341 healthy women aged 20-35 who wanted oral contraceptives. Had to have 2-5 previous births and prior successful breastfeeding experience of at least 3 months	No differences found in breastfeeding continuation rates, mean infant weight, length, or rate of growth, or infant illness were found between COC and control groups, except female infants at one site were smaller in controls than COC group. Milk from COC group was lower in calories, and had different mineral content; milk volume was lower than controls.	No adjustment for confounders. Loss to follow-up was high in some groups. Supplementation not addressed. Method switching not addressed.	WHO. Effects of hormonal contraceptives on breast milk composition and infant growth. World Health Organization (WHO) Task Force on Oral Contraceptives. Stud Fam Plann 1988 Nov-

							Dec;19(6 Pt 1):361-369.
WHO	Hungary and Thailand	Prospective Cohort/ RCT	6 weeks PP: N=86 COC (30 μg EE and 150 μg LNG N=85 POP (75 μg norgestrel) N=59 DMPA N=111 Non-hormonal (barriers, sterilization, IUDs)	N=341 healthy women aged 20-35 who wanted oral contraceptives. Had to have 2-5 previous births and prior successful breastfeeding experience of at least 3 months	No differences in breastfeeding continuation. Milk volume decreased over time for all groups, but COC to a greater extent.	No adjustment for confounders. Method switching not addressed.	Tankeyoon M, Dusitsin N, Chalapati S, Koetsawang S, Saibiang S, Sas M, et al. Effects of hormonal contraceptives on milk volume and infant growth. WHO Special Programme of Research, Development and

							Research Training in Human Reproduction Task force on oral contraceptives. Contraception 1984 Dec;30(6): 505-522.
Baheiraei et al.	(2001) Iran	Prospective cohort	6 weeks PP: N=51 Progesterone-only methods (DMPA or POP); N=89 Non-hormonal	N=140 healthy, term women	No differences between groups in infant weight of length.	Progesterone-only methods were grouped together.	Baheiraei A, Ardsetani N, Ghazizadeh S. Effects of progestogen-only contraceptives on breast-feeding and infant growth. Int J Gynaecol Obstet 2001 Aug;74(2): 203-205.

Implants

Study	Year and Location	Study Design	Exposure	Population	Results	Study problems	Reference
Brito et al	(2009) Brazil	RCT	N= received ETG implant 24-48 hours PP N= received 150 mg DMPA, 6 weeks PP	N=40 women with chronic disease, BMI<30, aged 18-35 years, no history of thromboembolism	At 12 weeks PP, no difference between implant and DMPA groups in exclusive breastfeeding rates (17/20 ETG, 15/20 DMPA), no differences in infant weight observed.	Comparison of one treatment to another treatment, combines time and treatment such that the two effects cannot be differentiated. Does not inform about either treatment relative to biological norm. Follow-up only to 12 weeks.	Brito MB, Ferriani RA, Quintana SM, Yazlle ME, Silva de Sa MF, Vieira CS. Safety of the etonogestrel-releasing implant during the immediate postpartum period: a pilot study. Contraception 2009 Dec;80(6):519-526.
Abdulla et al	(1985) Egypt	Cohort	30 and 39 days PP: N=LNG implant (Norplant); N=10 non-hormona	N=10 breastfeeding women, with singleton, term birth	No difference in immune factors seen at 5 months PP	Poor reporting of measures. Breastfeeding rates not reported.	Abdulla KA, Élan SI, Salem HS, Shaaban MM. Effect of early postpartum use of the contraceptive implants,

			l or no methods				NORPLANT, on the serum levels of immunoglobul ins of the mothers and their breastfed infants. Contraception 1985 Sep;32(3):261-266.
Abdel-Aleem et al	1992-94 Egypt	Cohort	2 months PP: N=120 nomeges trol subderm al implant (Uniplan t); N=120 Copper IUD	N=247 exclusively breastfeeding mothers who asked for contraception	No significant differences in episodes of breastfeeding, time of weaning, rates of exclusive and partial breastfeeding, infant weight , and infant growth between the two groups	No adjustment for confounding and groups differed at baseline due to self-selection of treatment.	Abdel-Aleem H, Abol-Oyoun el-S M, Shaaban MM, el-Saeed M, Shoukry M, Makhlouf A, et al. The use of nomegestrol acetate subdermal contraceptive implant, Uniplant, during lactation. Contraception 1996 Nov;54(5):281 -286.

			30 days PP: N=84 Progeste rone pellets (100mg) ; N=130 injectabl e placebo; N=125 Copper IUD	N=439 exclusively breastfeeding women, age 18-35	Duration of breastfeeding and child growth were the same in implant and control groups. At 6 months, the percentage of women fully breastfeeding was 51.2% for implant and 58.3% for IUD, and at 12 months 10.7% and 17.6% respectively (p<0.05).	Not Randomized. High loss to follow-up and discontinuation.	Croxatto HB, Diaz S, Peralta O, Juez G, Casado ME, Salvatierra AM, et al. Fertility regulation in nursing women. II. Comparative performance of progesterone implants versus placebo and copper T. Am J Obstet Gynecol 1982 Sep 15;144(2):201-208.
Croxatoo et al.	(1982) Chile	Cohort					
Diaz et al.	(1984) Chile	Cohort	30 days PP: N=84 Progeste rone pellets (100mg) ; N=130 injectabl e placebo;	N=439 healthy women, age 18-35, vaginal term delivery, willing to breastfeed as long as possible	No difference in continuation of breastfeeding or infant growth between groups	No adjustment for confounding. High loss to follow-up and discontinuation.	Diaz S, Peralta O, Juez G, Herreros C, Casado ME, Salvatierra AM, et al. Fertility regulation in nursing women. VI. Contraceptive

			N=125 Copper IUD. 60 days PP: N=193 Progesterone pellets (100mg); N=121 Copper IUD.				effectiveness of a subdermal progesterone implant. Contraception 1984 Oct;30(4):311-325.
Diaz et al.	(1985) Chile	Cohort	55 days PP: N=100 LNG implant (Norplant); N=100 Copper IUD	N=200 exclusively breastfeeding women with adequate infant weight gain	No significant difference between groups in percentage of women fully nursing, except for at 12 months when lower percentage of Norplant group was still fully nursing. No significant difference in infant weight gain except in the 4th month when female infants of	No adjustment for confounding.	Diaz S, Herreros C, Juez G, Casado ME, Salvatierra AM, Miranda P, et al. Fertility regulation in nursing women: VII. Influence of NORPLANT levonorgestrel implants upon lactation and infant growth. Contraception 1985 Jul;32(1):53-74.

					mothers with the implant had lower weight gain than the IUD group		
Diaz et al.	(1997) Chile	Cohort with historical controls	57 days PP: N=187 Progesterone Vaginal Ring; N=117 POP (lystrenol); N=120 LNG implant (Norplant); N=122 Copper IUD; N=236 LAM	N= healthy, cohabitating, 18-38 year-olds, with normal delivery and intending the breastfeed as long as possible	No difference between groups in mean duration of breastfeeding or time of weaning	Historical control	Diaz S, Zepeda A, Maturana X, Reyes MV, Miranda P, Casado ME, et al. Fertility regulation in nursing women. IX. Contraceptive performance, duration of lactation, infant growth, and bleeding patterns during use of progesterone vaginal rings, progestin-only pills, Norplant implants, and Copper T 380-A intrauterine devices.

							Contraception 1997 Oct;56(4):223-232.
Massai et al.	(2001) Chile	Prospective Cohort	8 weeks PP: N=100 NES; N=100 Copper IUD	N=200 cohabitating women, aged 18-38, who had term deliveries	No difference in episodes or duration of breastfeeding. No difference in infant growth	High discontinuation rate (17% for NES, 2% for IUD)	Massai MR, Diaz S, Quinteros E, Reyes MV, Herreros C, Zepeda A, et al. Contraceptive efficacy and clinical performance of Nestorone implants in postpartum women. Contraception 2001 Dec;64(6):369-376.

Taneepanic hskul et al	(2006) Thailand	Prospective cohort	28-56 days PP: N=42 etonoges trel implant (Implano n); N=38 copper IUD	N=80 healthy, fully breastfeeding women with healthy, singleton births	Mean duration of breastfeeding 421 days for Implanon and 423 for IUD users. No differences in child growth or development were observed.	No information on contraceptive switching or discontinuation or response rate for study participation	Taneepanichsk ul S, Reinprayoon D, Thaithumyano n P, Praisuwanna P, Tosukhowong P, Dieben T. Effects of the etonogestrel-releasing implant Implanon and a nonmedicated intrauterine device on the growth of breast-fed infants. Contraception 2006 Apr;73(4):368-371.
Reinprayoo n et al	(2000) Thailand	Prospective cohort	28-56 days PP: N=42 etonoges trel implant (Implano	N=80 healthy, fully breastfeeding women with healthy, singleton births	No differences in milk composition or volume between groups. No difference in	No information on contraceptive switching or discontinuation or response rate for study participation	Reinprayoon D, Taneepanichsk ul S, Bunyavejchevi n S, Thaithumyano

			n); N=38 copper IUD		timing or quantity of supplementation. No significant difference in infant growth or weight gain.		n P, Punnahitananda S, Tosukhowong P, et al. Effects of the etonogestrel-releasing contraceptive implant (Implanon on parameters of breastfeeding compared to those of an intrauterine device. Contraception 2000 Nov;62(5):239-246.
Schiappacasse et al	(2002) Chile	Prospective Cohort	55-60 days PP: N=220 LNG implant (Norplant); N=222 Copper IUD	N=442 cohabitating women, ages 18-35, after term delivery	Infants of Norplant users had higher rates of respiratory infections, skin conditions, and eye infections than the IUD group. No differences in breastfeeding	High loss to follow-up (14% implant, 21% IUD). Health outcomes could be attributable to urban pollution at study site.	Schiappacasse V, Diaz S, Zepeda A, Alvarado R, Herreros C. Health and growth of infants breastfed by Norplant contraceptive implants users:

					patterns or infant growth between groups.		a six-year follow-up study. Contraception 2002 Jul;66(1):57-65.
Seth et al	(1977) India	Cohort	Norethin drone acetate implant (40 mg): N=23 insertion at 6 days PP; N=12 insertion at 6 weeks PP; N=15 condoms /gel.	N=50 healthy, 20 to 40 year old, breastfeeding women	56.4% of implant group were supplementing at 3 months compared to 40% of controls (p<0.05) Short-term reduction in milk volume observed 2 weeks after insertion for early insertion group, as well as, a reduction in phosphorous content from 2 to 4 months. No difference in infant weights between	Small study size. Follow-up and baseline characteristics not reported.	Seth U, Yadava HS, Agarwal N, Laumas KR, Hingorani V. Effect of a subdermal silastic implant containing norethindrone acetate on human lactation. Contraception 1977 Oct;16(4):383-398.

					groups.		
Shaaban et al.	(1985) Egypt	Cohort	30-42 days PP: N=50 LNG implant (Norplant); N=Copper IUD; N=50 non-hormonal	N=150 breastfeeding women	No difference in duration of breastfeeding or rates of supplementation. Infant weight and height was less in the Norplant group at 3 months, but no significant difference at 6 months.	Differences between groups at baseline and no adjustment for confounders	Shaaban MM, Salem HT, Abdullah KA. Influence of levonorgestrel contraceptive implants, NORPLANT, initiated early postpartum upon lactation and infant growth. Contraception 1985 Dec;32(6):623-635.
Shaaban et al.	(1991) Egypt	Cohort	5-7 weeks PP: N=120 LNG implant (Norplant); N=120 NET-EN	Phase I: N=360 healthy women. Phase II: N=186 women	Phase I: No difference in supplementation timing. IUD users ceased breastfeeding earlier than NET-EN users. No difference in	Poor reporting of baseline characteristics, follow-up, and methods.	Shaaban MM. Contraception with progestogens and progesterone during lactation. J Steroid Biochem Mol

			injectable; N=120 IUD inserted in 2nd month PP; N=103 PVR; N=83 Copper IUD.		infant outcomes. Phase II: No difference in supplementation or infant growth between Vaginal ring and IUD users.		Biol 1991;40(4-6):705-710.
Shikary et al	(1986) India	Cohort	4-15 weeks PP: N=9 POP (LNG 30 μg/day); N=10 LNG implant (Norplant); N=10 no method	N=29 term women age 20-35 with male infants	No significant difference between groups in hormone levels present in urine from male infants	Short follow-up. Small study size.	Shikary ZK, Betrabet SS, Toddywala WS, Patel DM, Datey S, Saxena BN. Pharmacodynamic effects of levonorgestrel (LNG) administered either orally or supermall to early postpartum lactating mothers on the urinary levels of follicle stimulating

							hormone (FSH), luteinizing hormone (LH) and testosterone (T) in their breast-fed male infants. Contraception 1986 Oct;34(4):403-412.
WHO	(1994) Egypt, Iran, Thailand, Kenya, Chile, Hungary	Cohort	6-8 weeks PP: N=475 POP (LNG or lynestrenol); N=541 DMPA; N-121 NET-EN; N=453 LNG implant (Norplant); N=876 non-	N=2466 married women with term deliveries.	No difference in frequency and duration of breastfeeding between contraceptive types at the same site, but differences seen between locations. Infant growth and development outcomes were inconsistent between sites.	Breastfeeding outcomes varied greatly between sites.	Progestogen-only contraceptives during lactation: I. Infant growth. World Health Organization Task force for Epidemiological Research on Reproductive Health; Special Programme of Research, Development and Research Training in Human

			hormona l				Reproduction. Contraception 1994 Jul;50(1):35-53. Progestogen-only contraceptives during lactation: II. Infant development. World Health Organization, Task Force for Epidemiologic al Research on Reproductive Health; Special Programme of Research, Development, and Research Training in Human Reproduction. Contraception 1994 Jul;50(1):55-68.

Affandi et al.	(1986) India	Prospective cohort	4 -6 weeks PP: N=60 LNG implant (Norplant); N=60 Copper IUD	N=120 term women planning to breastfeed at least 6 months who had a healthy delivery. Ages 18-40 years.	Infants in the Norplant group gained significantly more than IUD group.	Differences between groups at baseline. No adjustment for confounders.	Affandi B, Karmadibrata S, Prihartono J, Lubis OF, Samil RS. Effect of Norplant on mothers and infants in the postpartum period. Adv Contracept 1986 Dec;2(4):371-380.
Gurtcheff et al	(2011) Utah	Randomized controlled trial	Etonogestrel implant (Implanon): N=35 insertion at 1-3 PP; N=34 insertion at 4-8 weeks PP	N= healthy, term women who wanted Implanon implant	Lactogenesis II was not statistically different between the early and late insertion groups, 64.3 vs. 65.2 hours PP. The groups were similar in their rate of lactation failure, 3% for early vs. 0% for standard timing of	Good randomization and design.	Gurtcheff SE, Turok DK, Stoddard G, Murphy PA, Gibson M, Jones KP. Lactogenesis after early postpartum use of the contraceptive implant: a randomized controlled trial. Obstet Gynecol 2011 May;117(5):1114-1121.

					insertion. Supplementation timing was also similar between groups.		
Coutinho et al	(1999) Brazil	Prospective cohort	6 weeks PP: N=66 elcometrine implant; N=69 Copper IUD	N=135 healthy, term women, ages 18-35, planning to breastfeed for at least 6 months.	Breastfeeding continuation rates were higher for implant than IUD group at 3 (95% vs. 84%) and 6 months (765 vs. 57%) (p<0.05), but no differences at 9 and 12 months. No differences in infant growth and development between groups.	No adjustment for confounding.	Coutinho EM, Athayde C, Dantas C, Hirsch C, Barbosa I. Use of a single implant of elcometrine (ST-1435), a nonorally active progestin, as a long acting contraceptive for postpartum nursing women. Contraception 1999 Feb;59(2):115-122.

Progesterone-only Pill (POP)

Study	Year and Location	Study Design	Exposure	Population	Results	Study problems	Reference
Guiloff et al	1974 Chile	randomized clinical trial/ case-only design with historical controls	At 30 days PP, randomized to receive: N=54 250 mg CMA; N=300 μg quingestanol acetate; N=81 IUD	N=696 16 to40 year-old, multiparous women	Median duration of breastfeeding for CMA use was 7.5 months vs. 4.2 months for quingestanol acetate, 5.3 months for historical control, and 7.7 months for Copper IUD.	Control group was the previous births from the same women. No further accounting for confounding.	Guiloff E, Ibarra-Polo A, Zanartu J, Toscanini C, Mischler TW, Gomez-Rogers C. Effect of contraception on lactation. Am J Obstet Gynecol 1974 Jan 1;118(1):42-45.
Halderman and Nelson	2002 Los Angeles, CA	Prospective cohort	women self-selected to receive DMPA before leaving the hospital (N=102), receive a prescription for POPs or LNG implant	N=319 women of all ages, parity, and prior breastfeeding experience	Women using hormonal contraception were significantly less likely to continue breastfeeding at 4 weeks (83.1% for non-hormonal, 76.7% for POCs,	No adjustment for confounding. Groups were significantly different in their prior breastfeeding experience, mother's age, and mode of delivery.	Halderman LD, Nelson AL. Impact of early postpartum administration of progestin-only hormonal

			(N=77) or use condoms or abstinence (N=138)		p=.022), but no difference was found at 2 and 6 weeks.		contraceptives compared with nonhormonal contraceptives on short-term breast-feeding patterns. Am J Obstet Gynecol 2002 Jun;186(6):1250-6; discussion 1256-8.
Giner et al	(1976) Mexico	RCT	Initiated within 14 hours of delivery N=12 received 350 μg NET; N=8 received placebo	20 healthy women, aged 18-36	No significant differences in initiation of breastfeeding, milk volume, or infant growth between treatment and placebo groups.	small sample size, methods not clearly described	Giner Velazquez J, Cortes Gallegos V, Sotelo Lopez A, Bondani G. Effect of daily oral administration of 0.350 mg of

							norethindrone on lactation and on the composition of milk. Ginecol Obstet Mex 1976 Jul;40(237):31-39.
Kamal et al.	(1970) Egypt	Clinical trial	2 days PP: N=10 POP (lynestrenol 500 µg); N=10 COC (100 µg mestranol and 1 mg lynestrenol); N=10 EE (100 µg); N=10 placebo	N=40 women, age 20-37	In 14 day follow-up, POP group initiated lactation earlier than placebo (3 vs. 5 days), had higher milk volume, and infant weight gain	Short follow-up. Not randomized. Small study size.	Kamal I, Hefnawi OF, Ghoneim M, Abdallah M, Abdel Razek S. Clinical, biochemical, and experimental studies on lactation. V. Clinical effects of steroids on the initiation of lactation. Am J

							Obstet Gynecol 1970 Oct 15;108(4):655-658.
Bjarnadottir et al	(2001) Iceland	Cohort	28-56 days PP: N=42 desogestrel (75 µg/day); N=41 Copper IUD	N=83 multiparous breastfeeding women, age 18-40. Term delivery and prior breastfeeding experience.	By the 7th cycle of follow-up, 78% of POP and 59% of IUD users were still breastfeeding. No differences in composition of milk and child growth and development over 2.5 year follow-up	Initiation of treatment varied over a long period of time.	Bjarnadottir RI, Gottfredsdottir H, Sigurdardottir K, Geirsson RT, Dieben TO. Comparative study of the effects of a progestogen-only pill containing desogestrel and an intrauterine contraceptive device in lactating women. BJOG 2001 Nov;108(11):1174-1180.

							Diaz S, Zepeda A, Maturana X, Reyes MV, Miranda P, Casado ME, et al. Fertility regulation in nursing women. IX. Contraceptive performance, duration of lactation, infant growth, and bleeding patterns during use of progesterone vaginal rings, progestin-only pills, Norplant
Diaz et al.	(1997) Chile	Cohort with historical controls	57 days PP: N=187 Progesterone Vaginal Ring; N=117 POP (lystrenol); N=120 LNG implant (Norplant); N=122 Copper IUD; N=236 LAM	N= healthy, cohabitating, 18-38 year-olds, with normal delivery and intending the breastfeed as long as possible	No difference between groups in mean duration of breastfeeding or time of weaning	Historical control	implants,

							and Copper T 380-A intrauterine devices. Contraception 1997 Oct;56(4):223-232.
McCann et al.	(1989) Argentina	non-randomized clinical trial	1 week PP: N=250 POP (LNG 30 µg/day); N=non-hormonal methods	N=500 healthy, multiparous women, ages 30-35, with prior breastfeeding experience	Infant weight gain was similar between treatment and control. POP users began supplementation significantly later than controls (5.4 months vs. 4.6) and also ceased breastfeeding later.	High loss to follow-up (55% at months)	McCann MF, Moggia AV, Higgins JE, Potts M, Becker C. The effects of a progestin-only oral contraceptive (levonorgestrel 0.03 mg) on breast-feeding. Contraception 1989 Dec;40(6):635-648.

McEwan et al	-1977	Clinical trial	N=22 200 µg twice daily; N=115 350 mcg of a novel chlormadione derivative	N=137 women including 43 who were breastfeedi ng	None of the breastfeeding women reported an effect on lactation	Lactation was not a primary outcome, and was only reported anecdotally	McEwan JA, Joyce DN, Tothill AU, Hawkins DF. Early experience in contracepti on with a new progestoge n. Contracepti on 1977 Oct;16(4):3 39-350.
Zanartu et al.	(1976) Chile	non-randomiz ed clinical trial	Weeks 3 to 10 PP: N=100 Chlormadinon e diacetate (0.6 mg/day); N=173 Copper IUD.	N=273 healthy women, ages 19-42	At 3 months, duration of breastfeeding was 98% for POP and 76% for IUD. At 6 months it was 80% and 56%, respectively. At 12 months it was 42% and 0%, respectively.	Subjects were grouped by breastfeeding motivation, making interpretation of the results difficult.	Zanartu J, Aguilera E, Munoz-Pinto G. Maintenanc e of lactation by means of continuous low-dose progestoge n given postpartum as a contracepti ve.

						Contraception 1976 Mar;13(3): 313-318.
Shikary et al	(1986) India	Cohort	4-15 weeks PP: N=9 POP (LNG 30 μg/day); N=10 LNG implant (Norplant); N=10 no method	N=29 term women age 20-35 with male infants	No significant difference between groups in hormone levels present in urine from male infants	Short follow-up. Small study size.	Shikary ZK, Betrabet SS, Toddywala WS, Patel DM, Datey S, Saxena BN. Pharmacodynamic effects of levonorgestrel (LNG) administered either orally or subdermally to early postpartum lactating mothers on the urinary levels of follicle stimulating hormone (FSH), luteinizing

							hormone (LH) and testosterone (T) in their breast-fed male infants. Contraception 1986 Oct;34(4):403-412.
West	(1983) Scotland	Cohort	N=114 norethisterone (.35 mg/day); N=89 unknown or no use.	N=203 women, fully breastfeeding at discharge (84 breastfeeding)	Most common reason for discontinuation of method was cessation of breastfeeding. No significant differences in breastfeeding rates at 3 and 6 months PP.	self-selection for contraceptive use	West CP. The acceptability of a progestagen-only contraceptive during breast-feeding. Contraception 1983 Jun;27(6):563-569.
Zacharias et al.	(1986) Chile	Prospective Cohort	2 to 4 months PP: N=143 LAM; N=109 IUD; N=228 DMPA; N=185 POP (Clogestone	N=665 term women who were willing to breastfeed	Median breastfeeding duration was 17 months for LAM and 19 months for IUD, DMPA, and POP combined.	Subjects self-selected treatment and no adjustment for confounders.	Zacharias S, Aguilera E, Assenzo JR, Zanartu J. Effects of hormonal

			Acetate .6 mg/day)		DMPA had the highest percentage of mothers nursing past 20 months.		and nonhormonal contraceptives on lactation and incidence of pregnancy. Contraception 1986 Mar;33(3): 203-213.
WHO	(1994) Egypt, Iran, Thailand, Kenya, Chile, Hungary	Cohort	6-8 weeks PP: N=475 POP (LNG or lynestrenol); N=541 DMPA; N-121 NET-EN; N=453 LNG implant (Norplant); N=876 non-hormonal	N=2466 married women with term deliveries.	No difference in frequency and duration of breastfeeding between contraceptive types at the same site, but differences seen between locations. Infant growth and development outcomes were inconsistent between sites.	Breastfeeding outcomes varied greatly between sites.	Progestogen-only contraceptives during lactation: I. Infant growth. World Health Organization Task force for Epidemiological Research on Reproductive Health; Special

							Programme of Research, Development and Research Training in Human Reproduction. Contraception 1994 Jul;50(1):35-53. Progestogen-only contraceptives during lactation: II. Infant development. World Health Organization, Task Force for Epidemiological Research on Reproductive Health; Special

							Programme of Research, Development, and Research Training in Human Reproduction. Contraception 1994 Jul;50(1):55-68.
WHO	Hungary and Thailand	RCT	Treatment began at 6 weeks PP N=86 COC (30 µg ethinyl estradiol and 150 µg levonorgestrel) N=85 POP (75 µg norgestrel) N=59 DMPA N=111 Non-hormonal (barriers, sterilization, IUDs)	N=341 healthy women aged 20-35 who wanted oral contraceptives. Had to have 2-5 previous births and prior successful breastfeeding experience of at least 3 months	No differences found in breastfeeding continuation rates, mean infant weight, length, or rate of growth, or infant illness were found between COC and control groups, except female infants at one site were smaller in controls than COC group. Milk from COC group was lower in calories, and had different	No adjustment for confounders. Loss to follow-up was high in some groups. Supplementation not addressed. Method switching not addressed.	WHO. Effects of hormonal contraceptives on breast milk composition and infant growth. World Health Organization (WHO) Task Force on Oral Contraceptives. Stud Fam Plann

					mineral content, an milk volume was lower than controls.		1988 Nov-Dec;19(6 Pt 1):361-369.
WHO	Hungary and Thailand	Prospective Cohort/ RCT	6 weeks PP: N=86 COC (30 μg EE and 150 μg LNG N=85 POP (75 μg norgestrel) N=59 DMPA N=111 Non-hormonal (barriers, sterilization, IUDs)	N=341 healthy women aged 20-35 who wanted oral contraceptives. Had to have 2-5 previous births and prior successful breastfeeding experience of at least 3 months	No differences in breastfeeding continuation. Milk volume decreased over time for all groups, but COC to a greater extent.	No adjustment for confounders. Method switching not addressed.	Tankeyoon M, Dusitsin N, Chalapati S, Koetsawang S, Saibiang S, Sas M, et al. Effects of hormonal contraceptives on milk volume and infant growth. WHO Special Programme of Research, Development and Research

							Training in Human Reproduction Task force on oral contraceptives. Contraception 1984 Dec;30(6): 505-522.

Vaginal Ring

Study	Year and Location	Study Design	Exposure	Population	Results	Study problems	Reference
Diaz et al.	(1997) Chile	Cohort with historical controls	57 days PP: N=187 Progesterone Vaginal Ring; N=117 POP (lystrenol); N=120 LNG implant (Norplant); N=122 Copper IUD; N=236 LAM	N= healthy, cohabitating, 18-38 year-olds, with normal delivery and intending the breastfeed as long as possible	No difference between groups in mean duration of breastfeeding or time of weaning	Historical control	Diaz S, Zepeda A, Maturana X, Reyes MV, Miranda P, Casado ME, et al. Fertility regulation in nursing women. IX. Contraceptive performance, duration of lactation, infant growth, and bleeding patterns during use of progesterone vaginal rings, progestin-only pills, Norplant implants, and Copper T 380-A intrauterine devices. Contraception 1997 Oct;56(4):223-

							232.
Massai et al.	(1999) Chile	Cohort	5-9 weeks PP: N=285 PVR; N=262 Copper IUD.	N=547 cohabitating, breastfeeding women aged 18-38, after term delivery	Similar breastfeeding duration, 257 for ring and 240 for IUD. Similar infant weight gain.	Large variation in time of initiation of use. Possible repeat reporting.	Massai R, Miranda P, Valdes P, Lavin P, Zepeda A, Casado ME, et al. Preregistration study on the safety and contraceptive efficacy of a progesterone-releasing vaginal ring in Chilean nursing women. Contraception 1999 Jul;60(1):9-14.
Massai et al	(2005) Chile	Cohort	54-64 days PP: N=192 PVR replaced after 4 months;	N=220 cohabitating, breastfeeding women aged 18-38, after	Mean duration of breastfeeding was 287 days for the 4-month group and 257 days for	comparison was made between different types of treatment,	Massai R, Quinteros E, Reyes MV, Caviedes R, Zepeda A,

			N=280 PVR replaced after for 3 months	term delivery	the 3-month group. Infant weight gain was similar between groups and in comparison to untreated women.	not to a no-treatment control	Montero JC, et al. Extended use of a progesterone-releasing vaginal ring in nursing women: a phase II clinical trial. Contraception 2005 Nov;72(5):352-357.
Shaaban et al.	(1991) Egypt	Cohort	5-7 weeks PP: N=120 LNG implant (Norplant); N=120 NET-EN injectable; N=120 IUD inserted in 2nd month PP; N=103 PVR; N=83 Copper IUD.	Phase I: N=360 healthy women. Phase II: N=186 women	Phase I: No difference in supplementation timing. IUD users ceased breastfeeding earlier than NET-EN users. No difference in infant outcomes. Phase II: No difference in supplementation or infant growth between Vaginal ring and IUD users.	Poor reporting of baseline characteristics, follow-up, and methods.	Shaaban MM. Contraception with progestogens and progesterone during lactation. J Steroid Biochem Mol Biol 1991;40(4-6):705-710.

							Sivin I, Diaz S, Croxatto HB, Miranda P, Shaaban M, Sayed EH, et al. Contraceptives for lactating women: a comparative trial of a progesterone-releasing vaginal ring and the copper T 380A IUD. Contraception 1997 Apr;55(4):225-232.
Sivin et al	(1997) Egypt, Singapore, USA, Chile, Sri Lanka	Cohort	29-63 days PP: N=802 PVR; N=734 Copper IUD	N=1536 healthy, term women age 18-35.	IUD users had higher breastfeeding continuation rates at 6 months and 1 year	Wide variation in initiation date. Centers were different at baseline.	

Levonorgestrel-releasing IUD (Mirena)

Study	Year and Location	Study Design	Exposure	Population	Results	Study problems	Reference
Shaamash et al	2001-2003 Assiut, Egypt	Randomized controlled trial	N=163 received Mirena (LNG-20 μg IUS) N=157 received Copper IUD (CuT380A IUD)	women in their 2nd month postpartum, exclusively breastfeeding and planned to nurse for at least a year, healthy term infants	Claimed no significant differences between Mirena and Copper IUD users on breastfeeding episodes, breastfeeding, full breastfeeding, partial breastfeeding, or weaning.	This population has a breastfeeding continuation rate at 1-year of 60-80% and is therefore not comparable to a US population. Across all categories, the Mirena group had lower breastfeeding rates than the Copper IUD, and more episodes of breastfeeding at 9 and 12 months.	Shaamash AH, Sayed GH, Hussien MM, Shaaban MM. A comparative study of the levonorgestrel-releasing intrauterine system Mirena versus the Copper T380A intrauterine device during lactation: breast-feeding performance, infant

							growth and infant development. Contraception 2005 Nov;72(5): 346-351.
Chen et al.	2007-08 Pittsburgh, PA	Prospective, randomized trial	N= 50 postplacental insertion of Mirena N=46 insertion of Mirena at 6-8 weeks postpartum	pregnant women over 18 years old who were interested in using Mirena after birth	Median breastfeeding duration was shorter for postplacental than for delayed insertion group (5 vs. 8.5 weeks). At six months, the delayed insertion group had a statistically significant (p=.02) difference in their continuation rate (11/46 vs. 3/50).	Study groups were similar in their social and demographic factors. Study may have been underpowered to see differences at earlier time-points. Comparison group allows for evaluation of timing of insertion, but not the effect of hormonal IUD use compared to no hormonal exposure.	Chen BA, Reeves MF, Creinin MD, Schwarz EB. Postplacental or delayed levonorgestrel intrauterine device insertion and breast-feeding duration. Contraception 2011 Nov;84(5): 499-504.

| Heikkilä and Luukainen | 1981 Helsinki, Finland | Prospective cohort | N=37 Nova-T copper IUD; N=29 LNG-releasing IUD 10 μg /day; N=34 LNG-releasing IUD 30 μg /day | N=110 Breastfeeding, Amenorrheic women at about 6 weeks postpartum (range 32-56 days) | At 75 days post-insertion,56% of the LNG-30 μg /day group continued to breastfeed compared with 79% for the Copper IUD group (<.05). These differences went away at later time points. Initiation of supplementary feeding occurred at 3.9 months on average in the Copper IUD group, and 3.4 months in the LNG-30 μg /day group. | Study participants self-selected the method used. Hormone exposure is different from that available in the US. Social context is different culturally and generationally. Methods not clearly described. | Heikkila M, Luukkainen T. Duration of breast-feeding and development of children after insertion of a levonorgestrel-releasing intrauterine contraceptive device. Contraception 1982 Mar;25(3): 279-292. |

Breastfeeding	Combined oral contraceptives (<35 μg ethinyl estradiol)	Combined contraceptive patch	Combined contraceptive vaginal ring	Combined injectable contraceptives[#]	Progesterone-only pills	Depot medroxyprogesterone acetate (DMPA) / norethisterone enantate (NET-EN)	Levonorgestrel and etonogestrel implants
<21 days	4 (4)	4 (4)	4 (4)	Not Available (4)	2 (3)	2 (3)	2 (3)
21 to <30 days							
w/o other risk factors for VTE	3 (4)	3 (4)	3 (4)	Not Available (4)	2 (3)	2 (3)	2 (3)
with other risk factors for VTE	3* (4)	3* (4)	3* (4)	Not Available (4)	2 (3)	2 (3)	2 (3)
30 to 42 days							
w/o other risk factors for VTE	2 (4)	2 (4)	2 (4)	Not Available (4)	1 (3)	1 (3)	1 (3)
with other risk factors for VTE	3* (4)	1 (4)	1 (4)	Not Available (4)	1 (3)	1 (3)	1 (3)
>=6 weeks to <6 months postpartum (primarily breastfeeding	2 (3)	2 (3)	2 (3)	Not Available (3)	1 (1)	1 (1)	1 (1)
>=6 months postpartum postpartum (in non-breastfeeding women)	2 (2)	2 (2)	2 (2)	Not Available (2)	1 (1)	1 (1)	1 (1)

<21 days					1 (1)	1 (1)	1 (1)
w/o other risk factors for VTE	4 (3)	4 (3)	4 (3)				
with other risk factors for VTE	4 (3/4)	4 (3/4)	4 (3/4)	Not available (3/4)			
21-42 days					1	1	1
w/o other risk factors for VTE	2 (2)	2 (2)	2 (2)	Not available (2)			
with other risk factors for VTE	3* (2/3)	3* (2/3)	3* (2/3)	Not available (2/3)			
>42 days	1	1	1	1	1	1	1

\# 1) Cyclofem = medroxyprogesterone acetate 25 mg plus estradiol cypionate 5 mg 2) Mesigyna = norethisterone enantate 50 mg plus estradiol valerate 5 mg
*"For women with other risk factors ofr VTE, these risk factors might increase the classification to "4"
VTE=venous thromboembolism

Postpartum (breastfeeding and non-breastfeeding women including cesarean section)	Copper-IUD	Levonorgestrel-releasing IUD (20 µg/day)
US = <10 minutes after placenta WHO = <48 hours including insertion immediately after delivery of the placenta		
breastfeeding	1 (1)	2(3)
non-breastfeeding	1 (1)	1 (1)
10 minutes (or 48 hours) to 4 weeks	2 (3)	2 (3)
> 4 weeks	1 (1)	1 (1)
puerperal sepsis	4 (4)	4 (4)

Summary from:

Jacobson JC, Aikins Murphy P. United States medical eligibility criteria for contraceptive use 2010: a review of changes. J Midwifery Womens Health 2011 Nov-Dec;56(6):598-607.

Centers for Disease Control and Prevention (CDC). U S. Medical Eligibility Criteria for Contraceptive Use, 2010. MMWR Recomm Rep 2010 Jun 18;59(RR-4):1-86.

World Health Organization. Medical eligibility criteria for contraceptive use. 2009.

# APPENDIX 6: FOREST PLOTS AND AIC AND BIC STATISTICS FOR THE MODEL WITH AND WITHOUT THE VARIABLE FOR INCOME

Sample drawn from a survey evaluating the Period of Purple Crying Intervention Program, 2010-11.
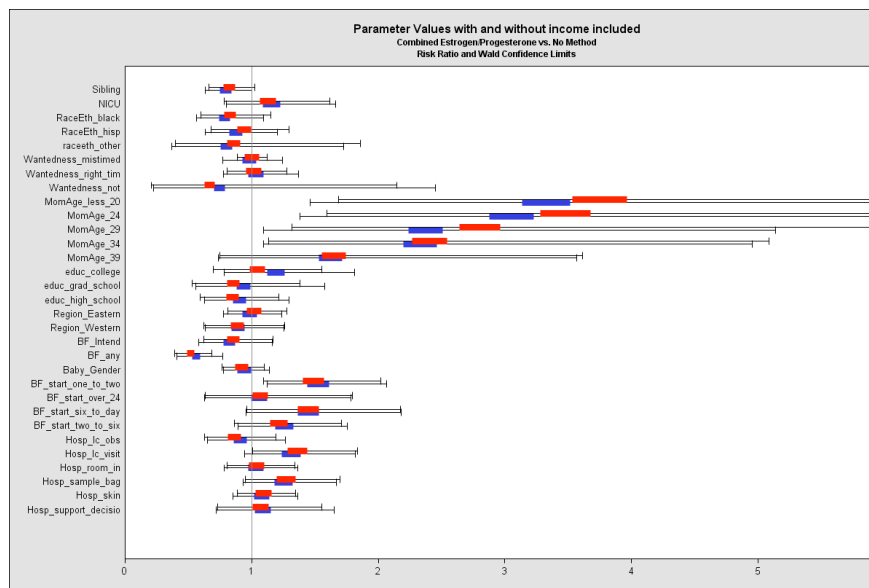
Progestin-only Methods vs. No Method
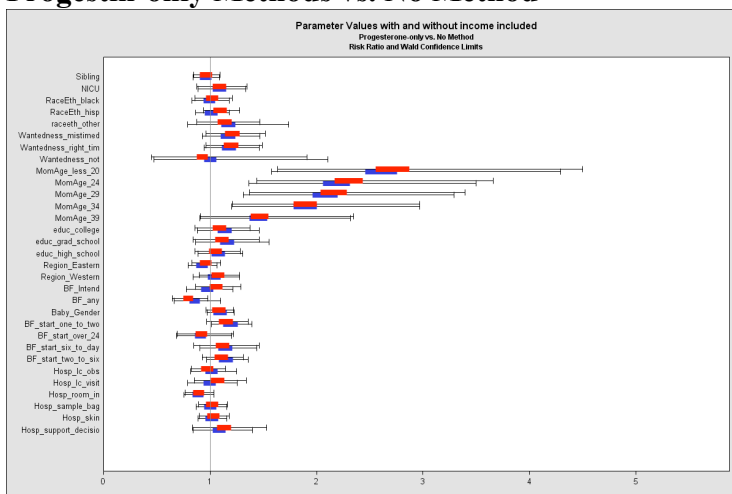
Criterion	Model1Stats	Model2Stats	LRChiSq	DF	pValue
Log Likelihood	-493.2568	-499.9317	13.3498	5	0.020312
Full Log Likelihood	-493.2568	-499.9317	13.3498	5	0.020312
AIC (smaller is better)	1058.5137	1061.8635	.	.	.
AICC (smaller is better)	1060.2606	1063.1602	.	.	.
BIC (smaller is better)	1251.2477	1227.8289	.	.	.

Progestin-only Methods vs. Non-hormonal Methods
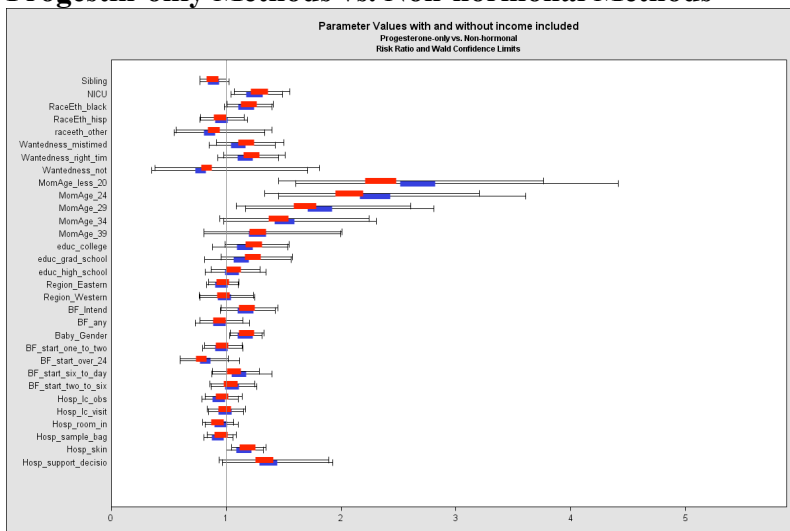
Criterion	Model1Stats	Model2Stats	LRChiSq	DF	pValue
Log Likelihood	-558.6153	-562.7562	8.28164	5	0.14138
Full Log Likelihood	-558.6153	-562.7562	8.28164	5	0.14138
AIC (smaller is better)	1189.2307	1187.5123	.	.	.
AICC (smaller is better)	1190.7732	1188.6578	.	.	.
BIC (smaller is better)	1386.3429	1357.2478	.	.	.

Combined Estrogen/Progestin Methods vs. No Method

Parameter Values with and without income included
Combined Estrogen/Progesterone vs. No Method
Risk Ratio and Wald Confidence Limits

Criterion	Model1Stats	Model2Stats	LRChiSq	DF	pValue
Log Likelihood	-325.0716	-328.6066	7.07001	5	0.21549
Full Log Likelihood	-325.0716	-328.6066	7.07001	5	0.21549
AIC (smaller is better)	722.1432	719.2132	.	.	.
AICC (smaller is better)	724.6541	721.0744	.	.	.
BIC (smaller is better)	902.1881	874.2519	.	.	.

Combined Estrogen/Progestin Methods vs. Non-hormonal Methods

Parameter Values with and without income included
Combined Estrogen/Progesterone vs. Non-hormonal
Risk Ratio and Wald Confidence Limits
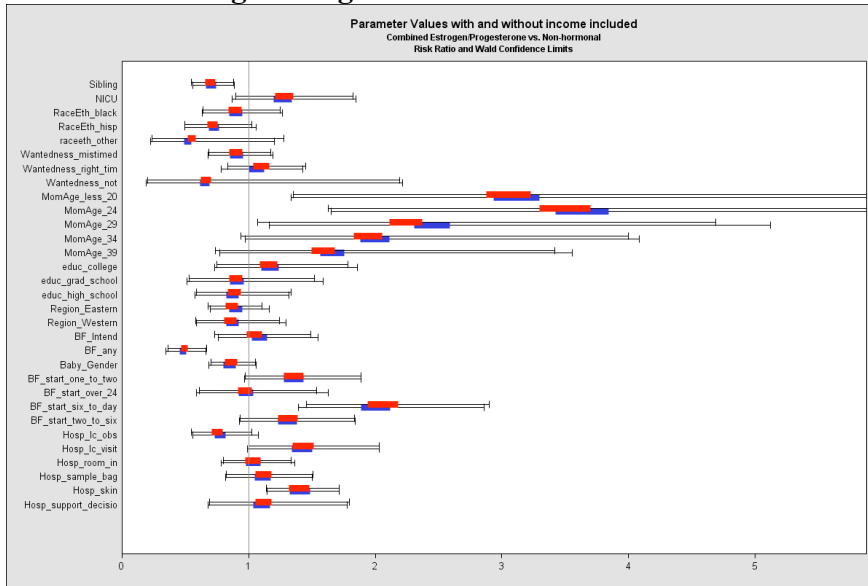
Criterion	Model1Stats	Model2Stats	LRChiSq	DF	pValue
Log Likelihood	-365.1640	-366.0708	1.81363	5	0.87428
Full Log Likelihood	-365.1640	-366.0708	1.81363	5	0.87428
AIC (smaller is better)	802.3280	794.1416	.	.	.
AICC (smaller is better)	804.4372	795.7063	.	.	.
BIC (smaller is better)	988.4523	954.4153	.	.	.

## Combined Estrogen/Progestin Methods vs. Progestin-only Methods
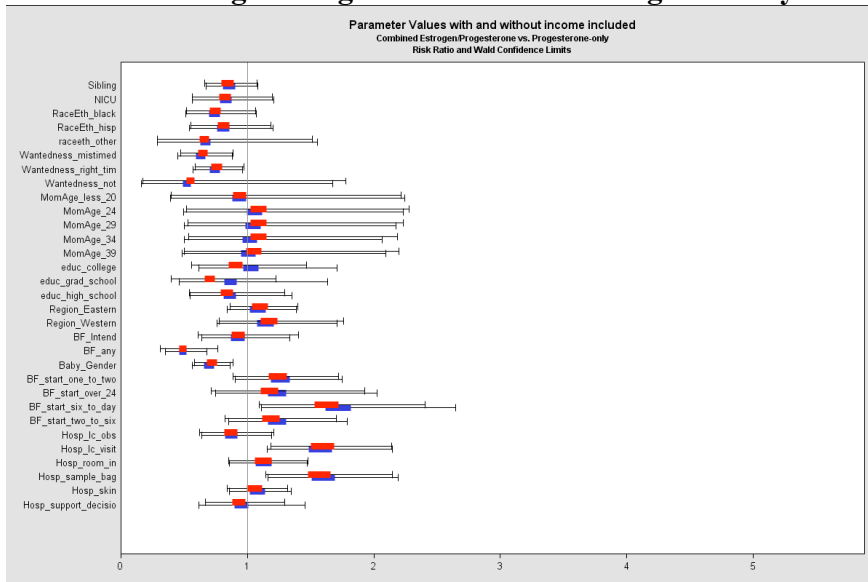
Parameter Values with and without income included
Combined Estrogen/Progesterone vs. Progesterone-only
Risk Ratio and Wald Confidence Limits

Criterion	Model1Stats	Model2Stats	LRChiSq	DF	pValue
Log Likelihood	-395.6693	-397.8071	4.27551	5	0.51047
Full Log Likelihood	-395.6693	-397.8071	4.27551	5	0.51047
AIC (smaller is better)	863.3387	857.6142	.	.	.

AICC (smaller is better)   865.3769   859.1264   .   .   .
BIC (smaller is better)   1050.6613   1018.9197   .   .   .

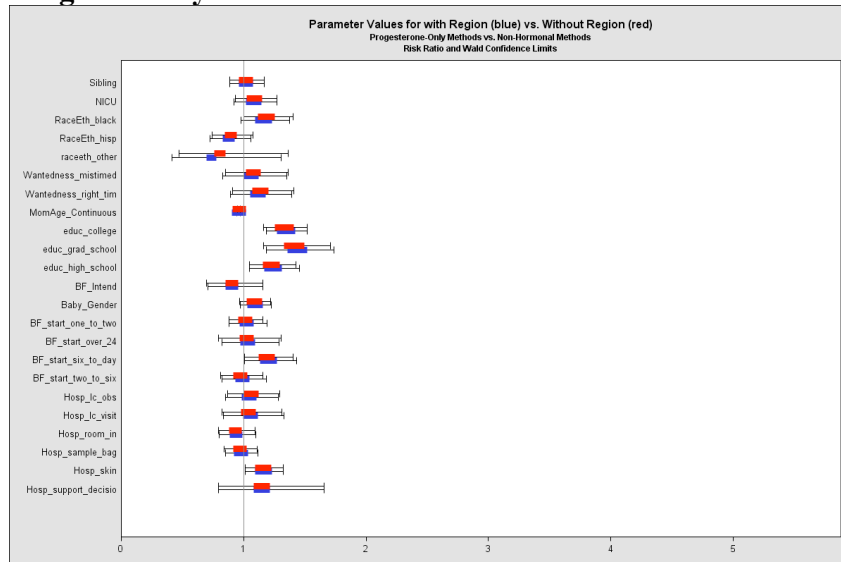# APPENDIX 7: FOREST PLOTS AND AIC AND BIC STATISTICS FOR THE MODEL WITH AND WITHOUT THE VARIABLE FOR REGION

Sample drawn from a survey evaluating the Period of Purple Crying Intervention Program, 2010-11.
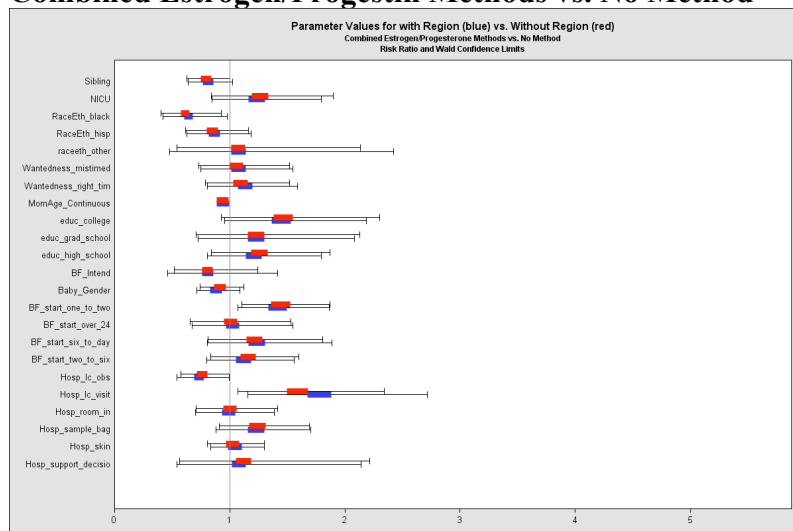
Progestin-only Methods vs. No Method
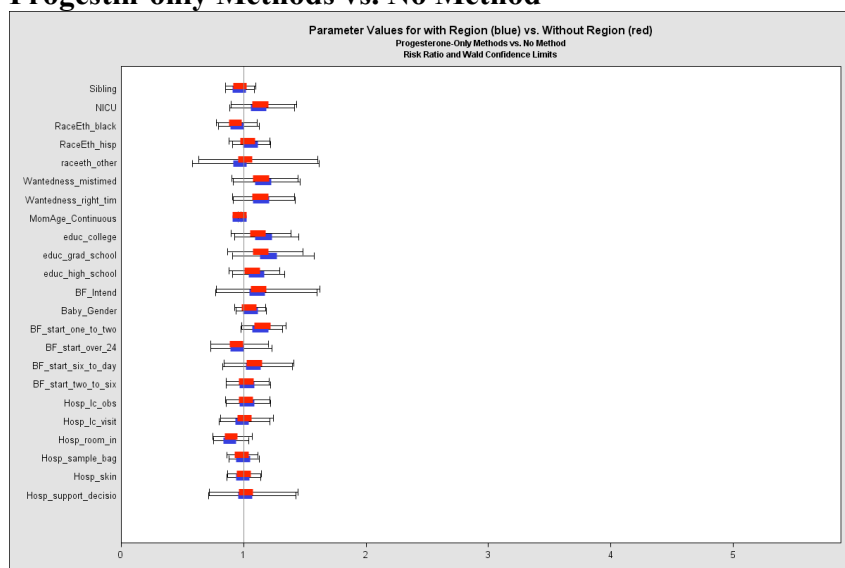
Criterion	Model1Stats	Model2Stats	LRChiSq	DF	pValue
Log Likelihood	-553.0112	-554.7398	3.45726	2	0.17753
Full Log Likelihood	-553.0112	-554.7398	3.45726	2	0.17753
AIC (smaller is better)	1168.0224	1167.4797	.	.	.
AICC (smaller is better)	1169.1881	1168.4984	.	.	.
BIC (smaller is better)	1337.2262	1325.8339	.	.	.

Progestin-only Methods vs. Non-hormonal Methods

Parameter Values for with Region (blue) vs. Without Region (red)
Progesterone-Only Methods vs. Non-Hormonal Methods
Risk Ratio and Wald Confidence Limits

Criterion	Model1Stats	Model2Stats	LRChiSq	DF	pValue
Log Likelihood	-625.3078	-628.3413	6.06689	2	0.048149
Full Log Likelihood	-625.3078	-628.3413	6.06689	2	0.048149
AIC (smaller is better)	1312.6157	1314.6826	.	.	.
AICC (smaller is better)	1313.6522	1315.5879	.	.	.
BIC (smaller is better)	1485.3951	1476.4042	.	.	.

Combined Estrogen/Progestin Methods vs. No Method

Parameter Values for with Region (blue) vs. Without Region (red)
Combined Estrogen/Progesterone Methods vs. No Method
Risk Ratio and Wald Confidence Limits

Criterion	Model1Stats	Model2Stats	LRChiSq	DF	pValue
Log Likelihood	-356.1844	-357.8901	3.41147	2	0.18164
Full Log Likelihood	-356.1844	-357.8901	3.41147	2	0.18164
AIC (smaller is better)	774.3688	773.7803	.	.	.

AICC (smaller is better)   776.0821   775.2751   .   .   .
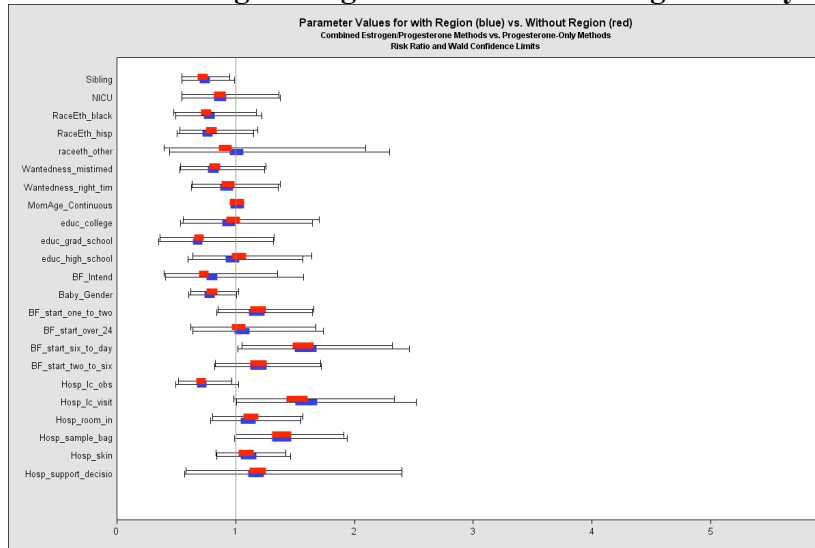BIC (smaller is better)   931.9018   921.2472   .   .   .

Combined Estrogen/Progestin Methods vs. Non-hormonal Methods
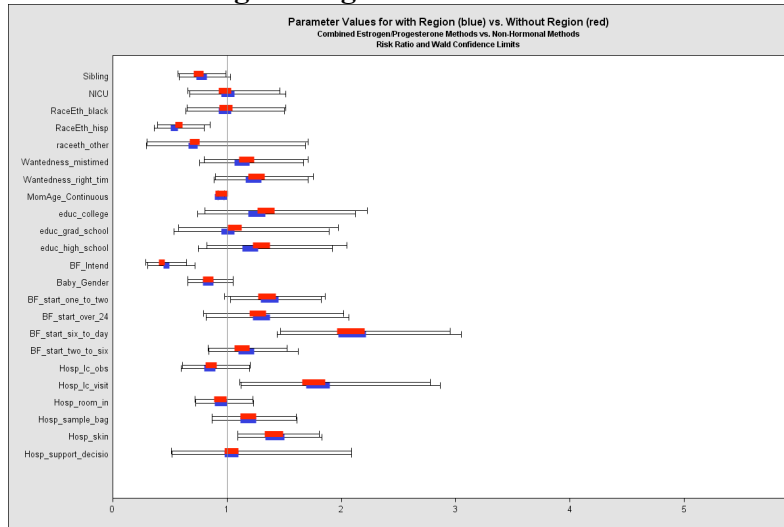
Parameter Values for with Region (blue) vs. Without Region (red)
Combined Estrogen/Progesterone Methods vs. Non-Hormonal Methods
Risk Ratio and Wald Confidence Limits

Criterion	Model1Stats	Model2Stats	LRChiSq	DF	pValue
Log Likelihood	-396.5502	-400.4088	7.71725	2	0.021097
Full Log Likelihood	-396.5502	-400.4088	7.71725	2	0.021097
AIC (smaller is better)	855.1003	858.8176	.	.	.
AICC (smaller is better)	856.5485	860.0803	.	.	.
BIC (smaller is better)	1017.7156	1011.0654	.	.	.

Combined Estrogen/Progestin Methods vs. Progestin-only Methods

Parameter Values for with Region (blue) vs. Without Region (red)
Combined Estrogen/Progesterone Methods vs. Progesterone-Only Methods
Risk Ratio and Wald Confidence Limits

Criterion	Model1Stats	Model2Stats	LRChiSq	DF	pValue
Log Likelihood	-436.3239	-440.0432	7.43860	2	0.024251
Full Log Likelihood	-436.3239	-440.0432	7.43860	2	0.024251
AIC (smaller is better)	934.6478	938.0864	.	.	.
AICC (smaller is better)	936.0142	939.2765	.	.	.
BIC (smaller is better)	1099.0252	1092.0147	.	.	.

APPENDIX 8: FOREST PLOTS AND AIC AND BIC STATISTICS FOR THE MODEL WITH MATERNAL AGE CODED AS CONTINUOUS OR BINNED
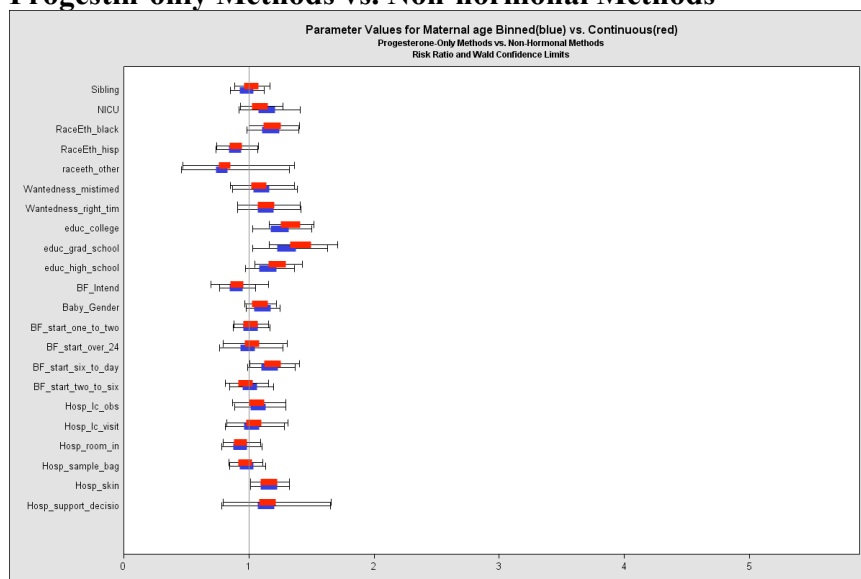
Sample drawn from a survey evaluating the Period of Purple Crying Intervention Program, 2010-11.

Progestin-only Methods vs. No Method
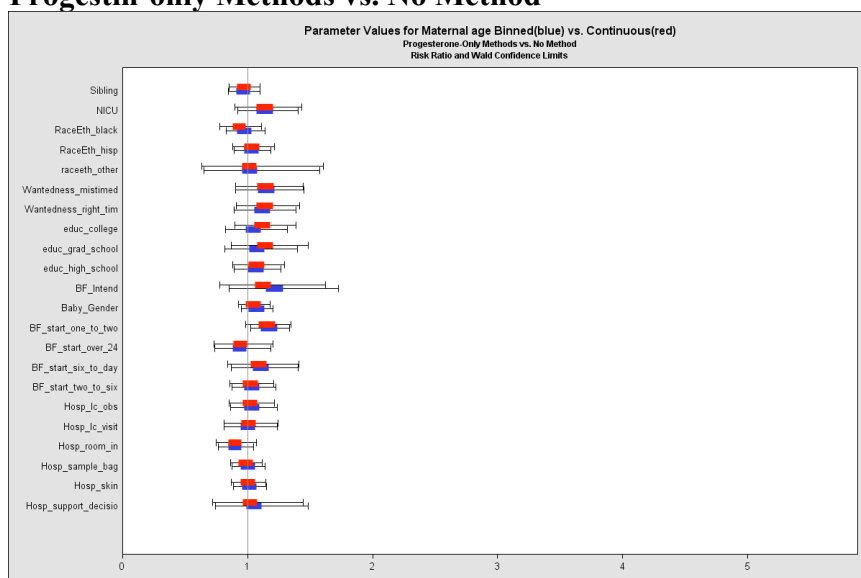
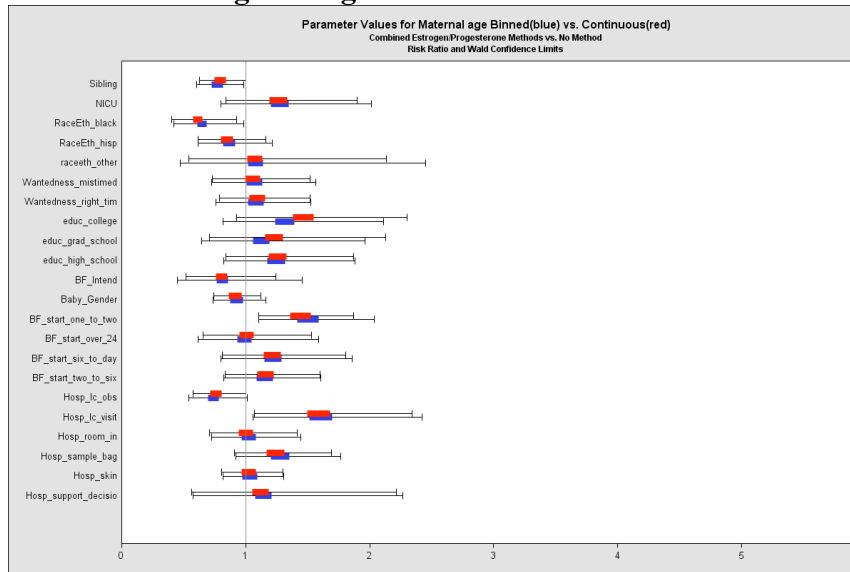| Criterion	Model1Stats	Model2Stats
AIC (smaller is better)	1017.8598	1017.1184
AICC (smaller is better)	1018.9698	1017.9364
BIC (smaller is better)	1166.4802	1144.5073

Progestin-only Methods vs. Non-hormonal Methods

Criterion	Model1Stats	Model2Stats

AIC (smaller is better)	1112.4625	1103.8397
AICC (smaller is better)	1113.4731	1104.5846
BIC (smaller is better)	1263.6628	1233.4399

Combined Estrogen/Progestin Methods vs. No Method

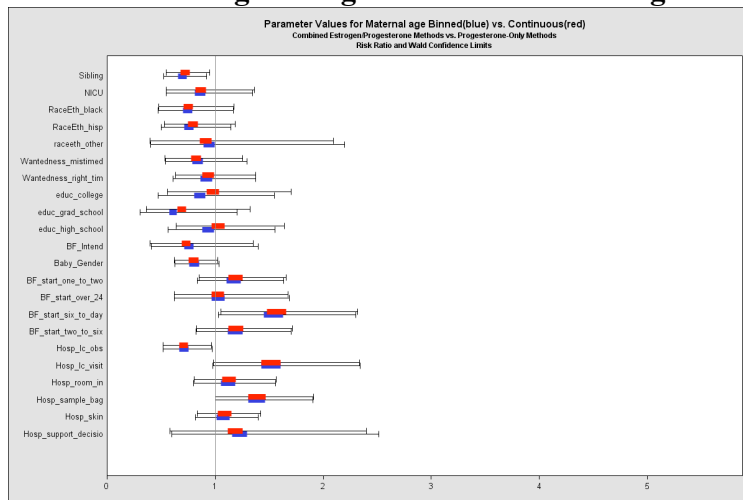| Criterion	Model1Stats	Model2Stats
AIC (smaller is better)	647.1861	637.7368
AICC (smaller is better)	648.8551	638.9650
BIC (smaller is better)	784.6592	755.5709

Combined Estrogen/Progestin Methods vs. Non-hormonal Methods
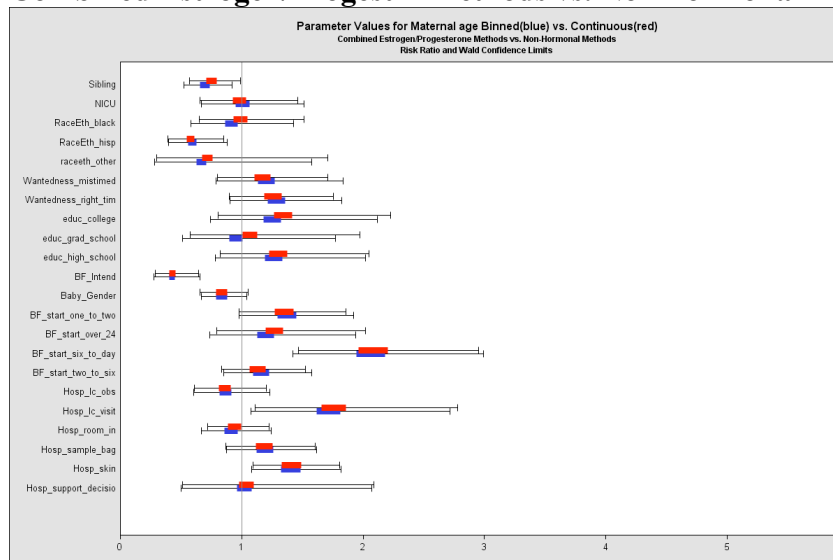
Criterion	Model1Stats	Model2Stats

AIC (smaller is better)	683.1848	671.6221
AICC (smaller is better)	684.6387	672.6926
BIC (smaller is better)	824.4178	792.6789

Combined Estrogen/Progestin Methods vs. Progestin-only Methods

Parameter Values for Maternal age Binned(blue) vs. Continuous(red)
Combined Estrogen/Progesterone Methods vs. Progesterone-Only Methods
Risk Ratio and Wald Confidence Limits

Criterion	Model1Stats	Model2Stats
AIC (smaller is better)	755.5663	749.0037
AICC (smaller is better)	756.9508	750.0232
BIC (smaller is better)	898.1351	871.2055

APPENDIX 9: COMPARISON OF CODING FOR HOSPITAL PRACTICES INDIVIDUALLY OR AS AN INDEX VARIABLE USING AIC AND BIC

Sample drawn from a survey evaluating the Period of Purple Crying Intervention Program, 2010-11.

Progesterone-Only Methods vs. No Method

Criterion	Model1Stats	Model2Stats
AIC (smaller is better)	1017.1184	1010.4220
AICC (smaller is better)	1017.9364	1010.9930
BIC (smaller is better)	1144.5073	1116.5794

Progesterone-Only Methods vs. Non-Hormonal Methods

Criterion	Model1Stats	Model2Stats
AIC (smaller is better)	1103.8397	1099.5674
AICC (smaller is better)	1104.5846	1100.0876
BIC (smaller is better)	1233.4399	1207.5676

Combined Estrogen/Progesterone Methods vs. No Method

Criterion	Model1Stats	Model2Stats
AIC (smaller is better)	637.7368	634.8197
AICC (smaller is better)	638.9650	635.6760
BIC (smaller is better)	755.5709	733.0148

Combined Estrogen/Progesterone Methods vs. Non-Hormonal Methods

Criterion	Model1Stats	Model2Stats
AIC (smaller is better)	671.6221	672.6603
AICC (smaller is better)	672.6926	673.4070
BIC (smaller is better)	792.6789	773.5410

Combined Estrogen/Progesterone Methods vs. Progesterone-Only Methods

Criterion	Model1Stats	Model2Stats
AIC (smaller is better)	749.0037	745.9313
AICC (smaller is better)	750.0232	746.6425
BIC (smaller is better)	871.2055	847.7661

APPENDIX 10: COMPARISON OF CODING FOR TIMING OF BREASTFEEDING INITIATION IN FIVE OR THREE CATEGORIES USING AIC AND BIC

Sample drawn from a survey evaluating the Period of Purple Crying Intervention Program, 2010-11.

Progesterone-Only Methods vs. No Method

Criterion	Model1Stats	Model2Stats
AIC (smaller is better)	1010.4220	1007.1690
AICC (smaller is better)	1010.9930	1007.6334
BIC (smaller is better)	1116.5794	1102.7107

Progesterone-Only Methods vs. Non-Hormonal Methods

Criterion	Model1Stats	Model2Stats
AIC (smaller is better)	1099.5674	1098.2950
AICC (smaller is better)	1100.0876	1098.7180
BIC (smaller is better)	1207.5676	1195.4952

Combined Estrogen/Progesterone Methods vs. No Method

Criterion	Model1Stats	Model2Stats
AIC (smaller is better)	634.8197	631.3394
AICC (smaller is better)	635.6760	632.0352
BIC (smaller is better)	733.0148	719.7149

Combined Estrogen/Progesterone Methods vs. Non-Hormonal Methods

Criterion	Model1Stats	Model2Stats
AIC (smaller is better)	672.6603	675.5626
AICC (smaller is better)	673.4070	676.1695
BIC (smaller is better)	773.5410	766.3552

Combined Estrogen/Progesterone Methods vs. Progesterone-Only Methods

| Criterion	Model1Stats	Model2Stats
AIC (smaller is better)	745.9313	743.4900
AICC (smaller is better)	746.6425	744.0682

BIC (smaller is better)   847.7661   835.1414

APPENDIX 11: CRUDE AND ADJUSTED SURVIVAL CURVES FOR PROGESTIN-ONLY METHODS COMPARED TO NON-HORMONAL OR NO METHOD OF CONTRACEPTION

From a survey evaluating the Period of Purple Crying intervention program, 2010-11, and limited to women who initiated breastfeeding. Adjusted curves are adjusted for maternal age, race/ethnicity, maternal education, pregnancy wantedness, parity, baby's gender, NICU stay, intention to breastfeed, timing of initiation, receipt of a formula sample bag, and hospital practices through propensity score weights.

Crude

Adjusted

Progestin-only Method vs. No Method

Crude

Adjusted
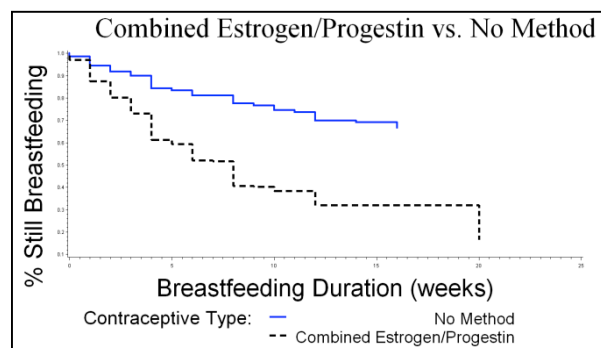

Progestin-only Method vs. Non-hormonal Methods

335
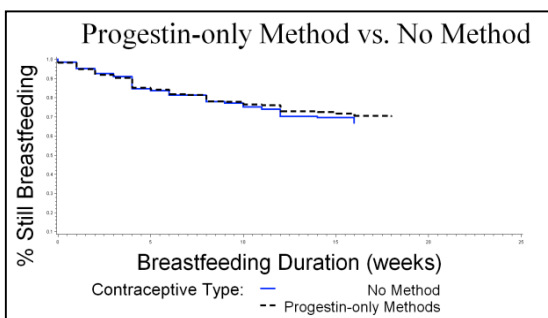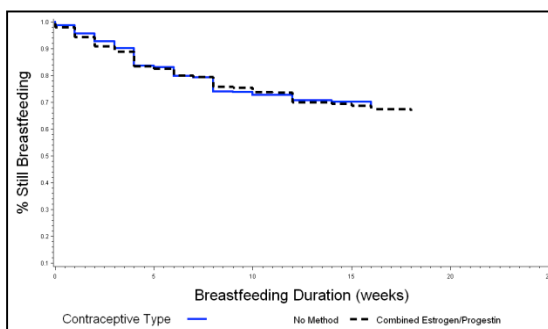
APPENDIX 12: CRUDE AND ADJUSTED SURVIVAL CURVES FOR COMBINED ESTROGEN/PROGESTIN METHODS COMPARED TO PROGESTIN-ONLY METHODS, NON-HORMONAL OR NO METHOD OF CONTRACEPTION

From a survey evaluating the Period of Purple Crying intervention program, 2010-11, and limited to women who initiated breastfeeding. Adjusted curves are adjusted for maternal age, race/ethnicity, maternal education, pregnancy wantedness, parity, baby's gender, NICU stay, intention to breastfeed, timing of initiation, receipt of a formula sample bag, and hospital practices through propensity score weights.
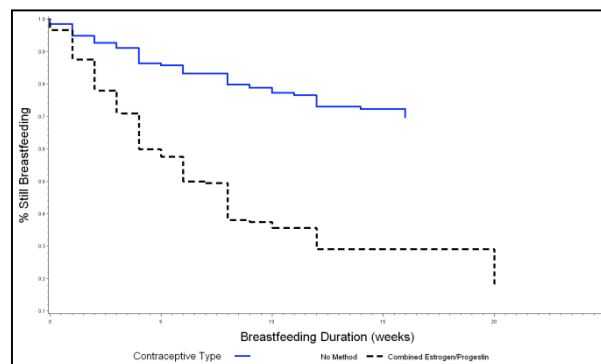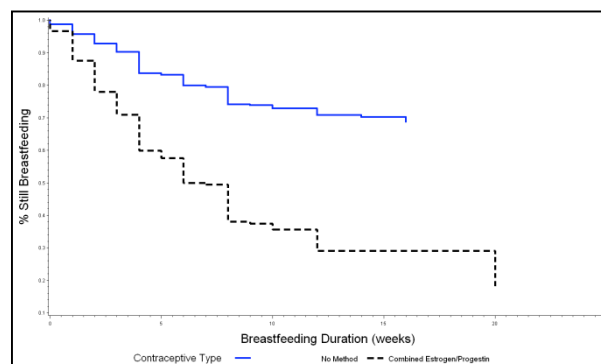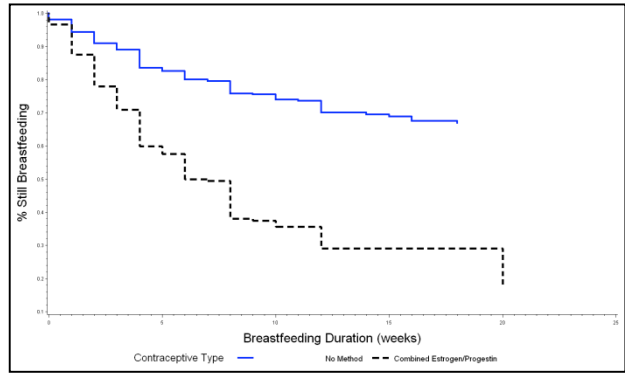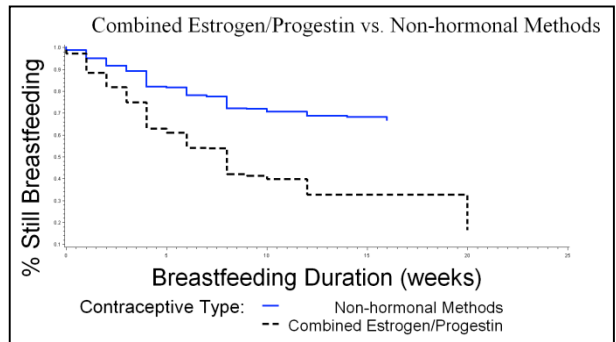
Crude
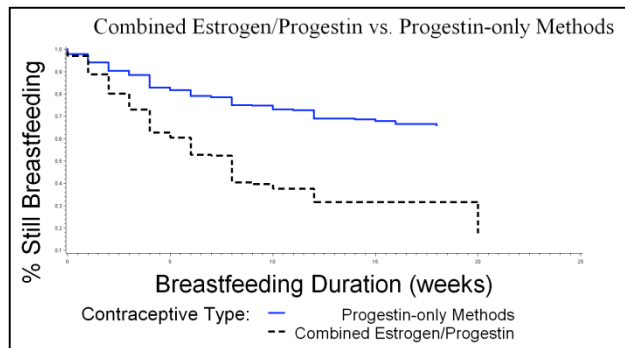

Adjusted

Crude

Adjusted

Crude

Combined Estrogen/Progestin vs. Non-hormonal Methods

Adjusted

Combined Estrogen/Progestin vs. Progestin-only Methods

337

APPENDIX 13: SURVEY QUESTIONNAIRE

A_INTRO First, I need to gather some background information.

A01. What is your child's name?
INTERVEWER NOTE: THE FOCUS OF THE SURVEY SHOULD BE A CHILD
YOUNGER THAN 9 MONTHS OLD, BORN IN NORTH CAROLINA, AND
CURRENTLY LIVING IN THE HOUSEHOLD. IF THERE IS MORE THAN ONE
CHILD THAT MEETS THIS CRITERIA, THE FOCUS SHOULD BE THE
YOUNGEST.
OPEN TEXT [50 CHARACTERS / REFUSED]

A02. I'm required to ask, is [BABY NAME] a boy or a girl?
INTERVIEWER: NO NEED TO ASK IF YOU ARE ALREADY CERTAIN OF THE
ANSWER
1.   BOY
2.   GIRL
8.   REFUSED

A03. How many months old is this child?
INTERVIEWER NOTE: FOR PARTIAL MONTHS (E.G. 6 WEEKS, 2 ½ MONTHS),
ASK THE R TO ROUND TO WHICHEVER IS THE CLOSER MONTH (E.G. 1
MONTH, 3 MONTHS); "Would you say s/he is closer to # month(s) or closer to #
months?"
INTERVIEWER NOTE: IT IS OKAY IF THE R REPORTS THAT THE YOUNGEST
CHILD MEETING THE ABOVE CRITERIA IS OLDER THAN 9 MONTHS,
CONFIRM CRITERIA, BUT CONTINUE THE SURVEY REGARDLESS OF AGE.
_____NUMBER OF MONTHS [RANGE 0 TO 99 / REFUSED]

A_INTRO2 We would like to ask you some questions about infant crying and
educational materials you may have received around the time of pregnancy, delivery, and
in the first months of your baby's life.

A10. In this first section, I am going to read some statements about young babies to
you, please tell me if you agree or disagree with them.
Do you agree or disagree with this statement: "Sometimes healthy babies may cry for 5
or more hours per day"?
1.   AGREE (GOTO A11)
2.   DISAGREE (GOTO A12)
8.   REFUSED (GOTO A20)
9.   DON'T KNOW (GOTO A20)

A11. Would you say that you agree very much or a little?
1.   AGREE VERY MUCH (GOTO A20)
2.   AGREE A LITTLE (GOTO A20)

8.   REFUSED (GOTO A20)
9.   DON'T KNOW (GOTO A20)

A12. Would you say that you disagree very much or a little?
1.   DISAGREE VERY MUCH (GOTO A20)
2.   DISAGREE A LITTLE (GOTO A20)
8.   REFUSED (GOTO A20)
9.   DON'T KNOW (GOTO A20)

A20. Do you agree or disagree with this statement: "Babies cry the <u>most</u> between 2 and 3 months of age"?
1.   AGREE (GOTO A21)
2.   DISAGREE (GOTO A22)
8.   REFUSED (GOTO A30)
9.   DON'T KNOW (GOTO A30)

A21. Would you say that you agree very much or a little?
1.   AGREE VERY MUCH (GOTO A30)
2.   AGREE A LITTLE (GOTO A30)
8.   REFUSED (GOTO A30)
9.   DON'T KNOW (GOTO A30)

A22. Would you say that you disagree very much or a little?
1.   DISAGREE VERY MUCH (GOTO A30)
2.   DISAGREE A LITTLE (GOTO A30)
8.   REFUSED (GOTO A30)
9.   DON'T KNOW (GOTO A30)

A30. (Do you agree or disagree with the following statement) How about: "A <u>good</u> parent should always be able to sooth his or her crying baby"?
1.   AGREE (GOTO A31)
2.   DISAGREE (GOTO A32)
8.   REFUSED (GOTO A40)
9.   DON'T KNOW (GOTO A40)

A31. Would you say that you agree very much or a little?
1.   AGREE VERY MUCH (GOTO A40)
2.   AGREE A LITTLE (GOTO A40)
8.   REFUSED (GOTO A40)
9.   DON'T KNOW (GOTO A40)

A32. Would you say that you disagree very much or a little?
1.   DISAGREE VERY MUCH (GOTO A40)
2.   DISAGREE A LITTLE (GOTO A40)
8.   REFUSED (GOTO A40)
9.   DON'T KNOW (GOTO A40)

A40. How about: "Shaking a baby is one way to help a baby stop crying"?
IF NEEDED: "By shaking we mean grabbing the baby and moving it back and forth strong enough that it could hurt the baby."
1.   AGREE (GOTO A41)
2.   DISAGREE (GOTO A42)
8.   REFUSED (GOTO A50)
9.   DON'T KNOW (GOTO A50)

A41. Would you say that you agree very much or a little?
1.   AGREE VERY MUCH (GOTO A50)
2.   AGREE A LITTLE (GOTO A50)
8.   REFUSED (GOTO A50)
9.   DON'T KNOW (GOTO A50)

A42. Would you say that you disagree very much or a little?
1.   DISAGREE VERY MUCH (GOTO A50)
2.   DISAGREE A LITTLE (GOTO A50)
8.   REFUSED (GOTO A50)
9.   DON'T KNOW (GOTO A50)

A50. Have you ever heard of a specific program or campaign called "The Period of Purple Crying"?
0.   NO (GOTO B_INTRO)
1.   YES (GOTO A51)
8.   REFUSED (GOTO B_INTRO)
9.   DON'T KNOW (GOTO B_INTRO)

A51. How did you hear about it? (CHECK ALL THAT APPLY)
INTERVIEWER: PROBE WITH "Anywhere else?" AS NEEDED
1.   AT THE HOSPITAL (GOTO B_INTRO)
2.   AT A COMMUNITY HEALTH CENTER OR HEALTH DEPARTMENT
        (GOTO B_INTRO)
3.   FROM NURSE VISITING IN MY HOME (GOTO B_INTRO)
4.   FROM THE MEDIA (GOTO B_INTRO)
5.   FROM A DOCTOR'S OFFICE (GOTO B_INTRO)
6.   FROM A FRIEND OR RELATIVE (GOTO B_INTRO)
7.   OTHER (GOTO A52)
8.   REFUSED (GOTO B_INTRO)
9.   DON'T KNOW (GOTO B_INTRO)

A52. SPECIFY OTHER SOURCE
OPEN TEXT [250 CHARACTERS]

B_INTRO   The Period of Purple Crying program is designed to help parents and people who care for infants understand the characteristics of normal infant crying, crying

which may be associated with shaken baby syndrome. For these next questions, try to think back to the days after [BABY NAME]'s birth.

B10. Did you learn about The Period of Purple Crying in the hospital or birth center?
INTERVIEWER NOTE: THIS IS INTENTIONALLY REDUNDANT. ASK EVEN IF A51 INDICATES HOSPITAL.
0.   NO
1.   YES
8.   REFUSED
9.   DON'T KNOW

B20. While in the hospital, did a nurse or healthcare provider talk to you about any of the following . . . (CHECK ALL THAT APPLY)
1.   that crying is normal?
2.   that shaking a baby is dangerous?
3.   that normal crying peaks at 2-3 months?
4.   about making sure to watch the DVD about normal infant crying at home?
5.   about making sure to read the booklet about normal infant crying at home?
6.   about sharing the information about crying and the dangers of shaking with others who will take care of your baby?
7.   NONE OF THE ABOVE
8.   REFUSED
9.   DON'T KNOW

B30. Did you watch a video about normal infant crying while in the hospital or birth center after your baby was born?
0.   NO (GOTO B60)
1.   YES (GOTO B40)
8.   REFUSED (GOTO B60)
9.   DON'T KNOW (GOTO B60)

B40. Did any family members or friends watch the video with you in the hospital?
0.   NO (GOTO B60)
1.   YES (GOTO B50)
8.   REFUSED (GOTO B60)
9.   DON'T KNOW (GOTO B60)

B50. Who watched the video with you in the hospital? (CHECK ALL THAT APPLY)
INTERVIEWER NOTE: IF R ANSWERS 'BOYFRIEND', ENTER 'BOYFRIEND'. IF R VOLUNTEERS THAT THE BOYFRIEND IS THE FATHER, ENTER 'FATHER'.
INTERVIEWER: PROBE WITH "Anyone else?" AS NEEDED
1.   [BABY NAME]'S FATHER (GOTO B60)
2.   [BABY NAME]'S SISTER/BROTHER (GOTO B60)
3.   [BABY NAME]'S STEPMOTHER (GOTO B60)
4.   [BABY NAME]'S STEPFATHER (GOTO B60)
5.   [BABY NAME]'S GRANDPARENT (GOTO B60)

6.   [BABY NAME]'S AUNT/UNCLE (GOTO B60)
7.   [BABY NAME] COUSIN (GOTO B60)
8.   FRIEND (GOTO B60)
9.   ANOTHER FAMILY MEMBER (GOTO B60)
10.   BOYFRIEND/GIRLFRIEND (GOTO B60)
11.   [BABY NAME]'S BABYSITTER (GOTO B60)
12.   OTHER (GOTO B51)
88.   REFUSED (GOTO B60)
99.   DON'T KNOW (GOTO B60)

B51. SPECIFY OTHER
OPEN TEXT [100 CHARACTERS]

B60. Did you get your own copy of a video and booklet about normal infant crying before leaving the hospital?
0.   NO (GOTO B65)
1.   YES (GOTO B65)
8.   REFUSED (GOTO B65)
9.   DON'T KNOW (GOTO B65)

B65. Do you have any way to watch DVDs at home?
0.   NO (IF B60=YES, GOTO B70; ELSE GOTO C10)
1.   YES (IF B60=YES, GOTO B70; ELSE GOTO C10)
8.   REFUSED (IF B60=YES, GOTO B70; ELSE GOTO C10)
9.   DON'T KNOW (IF B60=YES, GOTO B70; ELSE GOTO C10)

B70. Did you watch the video after leaving the hospital or birth center?
0.   NO
1.   YES
8.   REFUSED
9.   DON'T KNOW

B80. Did you look at the booklet after leaving the hospital or birth center?
IN NOTE: ENTER 'NO' IF R SAYS THEY RECEIVED THE VIDEO ONLY
0.   NO
1.   YES
8.   REFUSED
9.   DON'T KNOW

B90. Did you show the video to anyone after leaving the hospital?
0.   NO (GOTO B110)
1.   YES (GOTO B100)
8.   REFUSED (GOTO B110)
9.   DON'T KNOW (GOTO B110)

B100. Who did you show the video to? (CHECK ALL THAT APPLY)

INTERVIEWER NOTE: IF R ANSWERS 'BOYFRIEND', ENTER 'BOYFRIEND'. IF R VOLUNTEERS THAT THE BOYFRIEND IS THE FATHER, ENTER 'FATHER'.
INTERVIEWER: PROBE WITH "Anyone else?" AS NEEDED
1.   [BABY NAME]'S FATHER (GOTO B110)
2.   [BABY NAME]'S SISTER/BROTHER (GOTO B110)
3.   [BABY NAME]'S STEPMOTHER (GOTO B110)
4.   [BABY NAME]'S STEPFATHER (GOTO B110)
5.   [BABY NAME]'S GRANDPARENT (GOTO B110)
6.   [BABY NAME]'S AUNT/UNCLE (GOTO B110)
7.   [BABY NAME] COUSIN (GOTO B110)
8.   FRIEND (GOTO B110)
9.   ANOTHER FAMILY MEMBER (GOTO B110)
10.   BOYFRIEND/GIRLFRIEND (GOTO B110)
11.   [BABY NAME]'S BABYSITTER (GOTO B110)
12.   OTHER (GOTO B101)
88.   REFUSED (GOTO B110)
99.   DON'T KNOW (GOTO B110)

B101. SPECIFY OTHER
OPEN TEXT [50 CHARACTERS]

B110. Did you show the booklet to anyone after leaving the hospital?
IN NOTE: ENTER 'NO' IF R SAYS THEY RECEIVED THE VIDEO ONLY
0.   NO (GOTO C10)
1.   YES (GOTO B120)
8.   REFUSED (GOTO C10)
9.   DON'T KNOW (GOTO C10)

B120. Who did you show the booklet to? (CHECK ALL THAT APPLY)
INTERVIEWER NOTE: IF R ANSWERS 'BOYFRIEND', ENTER 'BOYFRIEND'. IF R VOLUNTEERS THAT THE BOYFRIEND IS THE FATHER, ENTER 'FATHER'.
INTERVIEWER: PROBE WITH "Anyone else?" AS NEEDED
1.   [BABY NAME]'S FATHER (GOTO C10)
2.   [BABY NAME]'S SISTER/BROTHER (GOTO C10)
3.   [BABY NAME]'S STEPMOTHER (GOTO C10)
4.   [BABY NAME]'S STEP FATHER (GOTO C10)
5.   [BABY NAME]'S GRANDPARENT (GOTO C10)
6.   [BABY NAME]'S AUNT/UNCLE (GOTO C10)
7.   [BABY NAME]'S COUSIN (GOTO C10)
8.   FRIEND (GOTO C10)
9.   ANOTHER FAMILY MEMBER (GOTO C10)
10.   BOYFRIEND/GIRLFRIEND (GOTO C10)
11.   [BABY NAME]'S BABYSITTER (GOTO C10)
12.   OTHER (GOTO B121)
88.   REFUSED (GOTO C10)
99.   DON'T KNOW (GOTO C10)

B121. SPECIFY OTHER
OPEN TEXT [50 CHARACTERS]

C10. During any visit to [BABY NAME]'s doctor's office or clinic, did anyone in the office speak with you about the characteristics of normal infant crying?
0.   NO
1.   YES
8.   REFUSED
9.   DON'T KNOW

C20. Did you receive written information about normal infant crying at your baby's doctor's office or clinic?
0.   NO (GOTO C30)
1.   YES (GOTO C21)
8.   REFUSED (GOTO C30)
9.   DON'T KNOW (GOTO C30)

C21. What did you do with that information? Did you . . . (CHECK ALL THAT APPLY)
1.   Read it?
2.   Share it with anyone?
3.   Save it?
4.   NONE OF THE ABOVE
8.   REFUSED
9.   DON'T KNOW

C30. Did you see a poster about normal infant crying at [BABY NAME]'s doctor's office or clinic?
0.   NO
1.   YES
8.   REFUSED
9.   DON'T KNOW

C40. In the past 12 months, have you seen any information about normal infant crying in . . . (CHECK ALL THAT APPLY)
1.   a newspaper story?
2.   a newspaper advertisement?
3.   a poster?
4.   a billboard?
5.   on the radio?
6.   on television?
7.   on the internet?
8.   NONE OF THE ABOVE
88.   REFUSED
99.   DON'T KNOW

C50. Have you seen or received information about normal infant crying anywhere else?
0.　　NO (GOTO D_INTRO)
1.　　YES (GOTO C51)
8.　　REFUSED (GOTO D_INTRO OR E_INTRO)
9.　　DON'T KNOW (GOTO D_INTRO OR E_INTRO)

C51.　Where else have you seen or received this information? (CHECK ALL THAT APPLY)
1.　　DURING PRENATAL CARE (GOTO D_INTRO OR E_INTRO)
2.　　DURING BIRTH EDUCATION (GOTO D_INTRO OR E_INTRO)
3.　　FROM A PROFESSIONAL HOME VISITOR LIKE A NURSE OR SOCIAL WORKER (GOTO D_INTRO OR E_INTRO)
4.　　IN THE EMERGENCY DEPARTMENT (GOTO D_INTRO OR E_INTRO)
5.　　AT WIC OR WOMEN, INFANT, AND CHILDREN'S NUTRITION PROGRAM (GOTO D_INTRO OR E_INTRO)
6.　　AT SOCIAL SERVICES (GOTO D_INTRO OR E_INTRO)
7.　　AT DAY CARE (GOTO D_INTRO OR E_INTRO)
8.　　FROM FRIENDS OR FAMILY MEMBERS (GOTO D_INTRO OR E_INTRO)
9.　　OTHER (GOTO C52)
88.　 REFUSED (GOTO D_INTRO OR E_INTRO)
99.　 DON'T KNOW (GOTO D_INTRO OR E_INTRO)

C52. SPECIFY OTHER
OPEN TEXT [100 CHARACTERS]

IF ANY OF THE FOLLOWING QUESTIONS WERE ANSWERED 1: A50, B10, B30, B70, B80, C10, C20, C30 OR B20 RESPONSES 1-6, C40 RESPONSES 1-7, OR C51 RESPONSES 1-9, ASK THE FOLLOWING QUESTIONS; ELSE, GOTO E_INTRO

D_INTRO　　Thinking about what you have learned about the characteristics of normal infant crying, please tell me if you agree or disagree with the following series of statements:

D10. "Learning about normal infant crying helped me to feel less frustrated when my baby was crying." (Do you agree or disagree with this statement?)
1.　　AGREE (GOTO D11)
2.　　DISAGREE (GOTO D12)
8.　　REFUSED (GOTO D20)
9.　　DON'T KNOW (GOTO D20)

D11. Would you say that you agree very much or a little?
1.　　AGREE VERY MUCH (GOTO D20)
2.　　AGREE A LITTLE (GOTO D20)
8.　　REFUSED (GOTO D20)
9.　　DON'T KNOW (GOTO D20)

D12. Would you say that you disagree very much or a little?
1.　　DISAGREE VERY MUCH (GOTO D20)
2.　　DISAGREE A LITTLE (GOTO D20)
8.　　REFUSED (GOTO D20)
9.　　DON'T KNOW (GOTO D20)

D20. "Learning about normal infant crying helped me to understand that my otherwise healthy baby's crying can be very normal even if it goes on for hours." (Do you agree or disagree with this statement?)
1.　　AGREE (GOTO D21)
2.　　DISAGREE (GOTO D22)
8.　　REFUSED (GOTO D30)
9.　　DON'T KNOW (GOTO D30)

D21. Would you say that you agree very much or a little?
1.　　AGREE VERY MUCH (GOTO D30)
2.　　AGREE A LITTLE (GOTO D30)
8.　　REFUSED (GOTO D30)
9.　　DON'T KNOW (GOTO D30)

D22. Would you say that you disagree very much or a little?
1.　　DISAGREE VERY MUCH (GOTO D30)
2.　　DISAGREE A LITTLE (GOTO D30)
8.　　REFUSED (GOTO D30)
9.　　DON'T KNOW (GOTO D30)

D30. "Learning about normal infant crying made me less stressed when my baby was crying." (Do you agree or disagree with this statement?)
1.　　AGREE (GOTO D31)
2.　　DISAGREE (GOTO D32)
8.　　REFUSED (GOTO D40)
9.　　DON'T KNOW (GOTO D40)

D31. Would you say that you agree very much or a little?
1.　　AGREE VERY MUCH (GOTO D40)
2.　　AGREE A LITTLE (GOTO D40)
8.　　REFUSED (GOTO D40)
9.　　DON'T KNOW (GOTO D40)

D32. Would you say that you disagree very much or a little?
1.　　DISAGREE VERY MUCH (GOTO D40)
2.　　DISAGREE A LITTLE (GOTO D40)
8.　　REFUSED (GOTO D40)
9.　　DON'T KNOW (GOTO D40)

D40. "The information about the characteristics of normal infant crying was new to me when my baby was born." (Do you agree or disagree with this statement?)
1. AGREE (GOTO D41)
2. DISAGREE (GOTO D42)
8. REFUSED (GOTO D70)
9. DON'T KNOW (GOTO D70)

D41. Would you say that you agree very much or a little?
1. AGREE VERY MUCH (GOTO D70)
2. AGREE A LITTLE (GOTO D70)
8. REFUSED (GOTO D70)
9. DON'T KNOW (GOTO D70)

D42. Would you say that you disagree very much or a little?
1. DISAGREE VERY MUCH (GOTO D70)
2. DISAGREE A LITTLE (GOTO D70)
8. REFUSED (GOTO D70)
9. DON'T KNOW (GOTO D70)

D70. "Learning about normal infant crying made me more likely to leave my infant alone in a safe place when I was frustrated with the crying." (Do you agree or disagree with this statement?)
1. AGREE (GOTO D71)
2. DISAGREE (GOTO D72)
8. REFUSED (GOTO D50 OR E_INTRO)
9. DON'T KNOW (GOTO D50 OR E_INTRO)

D71. Would you say that you agree very much or a little?
1. AGREE VERY MUCH (GOTO D50 OR E_INTRO)
2. AGREE A LITTLE (GOTO D50 OR E_INTRO)
8. REFUSED (GOTO D50 OR E_INTRO)
9. DON'T KNOW (GOTO D50 OR E_INTRO)

D72. Would you say that you disagree very much or a little?
1. DISAGREE VERY MUCH (GOTO D50 OR E_INTRO)
2. DISAGREE A LITTLE (GOTO D50 OR E_INTRO)
8. REFUSED (GOTO D50 OR E_INTRO)
9. DON'T KNOW (GOTO D50 OR E_INTRO)

ASK D50 AND D60 ONLY IF B20 OPTIONS 4 AND/OR 5 ARE CHECKED OR B30=1 OR B60=1; ELSE, GOTO E_INTRO

D50. "It is important for me to be able to use my own copy of the DVD and booklet at home."   (Do you agree or disagree with this statement?)
1. AGREE (GOTO D51)
2. DISAGREE (GOTO D52)

8. REFUSED (GOTO D60)
9. DON'T KNOW (GOTO D60)

D51. Would you say that you agree very much or a little?
1. AGREE VERY MUCH (GOTO D60)
2. AGREE A LITTLE (GOTO D60)
8. REFUSED (GOTO D60)
9. DON'T KNOW (GOTO D60)

D52. Would you say that you disagree very much or a little?
1. DISAGREE VERY MUCH (GOTO D60)
2. DISAGREE A LITTLE (GOTO D60)
8. REFUSED (GOTO D60)
9. DON'T KNOW (GOTO D60)

D60. "It is important for me to have my own copy of the DVD and booklet at home to share with my baby's other caregivers." (Do you agree or disagree with this statement?)
1. AGREE (GOTO D61)
2. DISAGREE (GOTO D62)
8. REFUSED (GOTO E_INTRO)
9. DON'T KNOW (GOTO E_INTRO)

D61. Would you say that you agree very much or a little?
1. AGREE VERY MUCH (GOTO E_INTRO)
2. AGREE A LITTLE (GOTO E_INTRO)
8. REFUSED (GOTO E_INTRO)
9. DON'T KNOW (GOTO E_INTRO)

D62. Would you say that you disagree very much or a little?
1. DISAGREE VERY MUCH (GOTO E_INTRO)
2. DISAGREE A LITTLE (GOTO E_INTRO)
8. REFUSED (GOTO E_INTRO)
9. DON'T KNOW (GOTO E_INTRO)

E_INTRO I am now going to ask you a few questions about understanding and feeding your infant, and about birth control.

E10. How do you know when [BABY NAME] is too stimulated or overwhelmed? Does [he/she/he or she] . . . (CHOOSE ALL THAT APPLY)
1. turn [his/her/his or her] head away? (GOTO E20)
2. cry? (GOTO E20)
3. become red or flushed? (GOTO E20)
4. go to sleep? (GOTO E20)
5. or something else? (GOTO E11)
8 REFUSED (GOTO E20)
9 DON'T KNOW (GOTO E20)

E11. SPECIFY OTHER
OPEN TEXT [150 CHARACTERS]

E20. Before [BABY NAME] was born, did you <u>intend</u> to breastfeed?
0.   NO (GOTO E22)
1.   YES (GOTO E21)
8.   REFUSED (GOTO E22)
9.   DON'T KNOW (GOTO E22)

E21. How long did you <u>intend</u> to breastfeed [BABY NAME]?
ENTER NUMBER OF WEEKS (IF ANSWER GIVEN IN MONTHS, MULTIPLY BY 4)
ENTER 0 FOR LESS THAN ONE WEEK
_____WEEKS [RANGE 0 TO 300 / REFUSED / DON'T KNOW]

E22. Did you ever breast feed [BABY NAME]?
0.   NO (GOTO E30)
1.   YES (GOTO E23)
8.   REFUSED (GOTO E30)
9.   DON'T KNOW (GOTO E30)

E23. When [BABY NAME] was born, how many hours was it until the first breastfeeding?
1.   <1 HOUR
2.   1-2 HOURS
3.   >2-6 HOURS
4.   >6-24 HOURS
5.   >24 HOURS
8.   REFUSED
9.   DON'T KNOW

E24. Are you still breastfeeding [BABY NAME]?
0.   NO (GOTO E25)
1.   YES (GOTO E26)
8.   REFUSED (GOTO E25)
9.   DON'T KNOW (GOTO E25)

E25.   How long did you breastfeed [BABY NAME]?
ENTER NUMBER OF WEEKS
_____WEEKS [RANGE 0 TO 396 / REFUSED / DON'T KNOW] (GOTO E30)
{HARD CHECK IF > A03 x 4}

E26. Is [BABY NAME] being fed other foods, formula or liquids other than breast milk more than once or twice a week?
0.   NO (GOTO E30)

1.	YES (GOTO E27)
8.	REFUSED (GOTO E30)
9.	DON'T KNOW (GOTO E30)

E27. At what age was [BABY NAME] first fed other foods, formula or liquids other than breast milk more than once or twice a week?
ENTER AGE IN WEEKS
_____WEEKS OF AGE WHEN OTHER FOODS ADDED WITH SOME
REGULARITY [RANGE 0 TO 396 / REFUSED / DON'T KNOW]
{HARD CHECK IF > A03 x 4}

E30. When [BABY NAME] was born . . . (CHECK ALL THAT APPLY)
IF NEEDED FOR OPTION 2-4: "All new mothers are supposed to be visited and supported by lactation consultants regardless of whether or not they intend to breastfeed, so we're asking everyone these questions."
1.	was [he/she/he or she] placed immediately on your skin?
2.	did a lactation consultant or breastfeeding specialist visit you and help you breast feed?
3.	did a lactation consultant or breastfeeding specialist observe you feeding [BABY NAME]?
4.	did you feel supported by all hospital staff in your decision regarding breastfeeding?
5.	was [BABY NAME] with you at least 22 hours of each 24 hour day?
6.	did you receive a bag with formula samples when you left the hospital?
7.	NONE OF THE ABOVE
8.	REFUSED
9.	DON'T KNOW

E40. Before leaving the hospital, did someone teach you how to care for [BABY NAME]'s umbilical cord?
0.	NO
1.	YES
8.	REFUSED
9.	DON'T KNOW

E50. Before leaving the hospital, did someone talk to you about safe infant sleep?
'SAFE INFANT SLEEP' = 'on back, no comforters, pillows, or stuffed animals'
0.	NO
1.	YES
8.	REFUSED
9.	DON'T KNOW

E60. Did [BABY NAME] spend any time in the neonatal intensive care unit or "NICU" before being discharged from the hospital?
INTERVIEWER NOTE: NICU IS PRONOUNCE "NICK-YOU"

IF R IS UNSURE WHAT THE NICU IS, ASK: "Did [BABY NAME] ever have to leave the maternity ward to be taken someplace for sick or fragile babies?"
0.   NO
1.   YES
8.   REFUSED
9.   DON'T KNOW

E70. Would you say your <u>pregnancy</u> with [BABY NAME] . . .
1.   was wanted <u>and</u> occurred at about the time you planned,
2.   was wanted, but not at this time,
3.   was wanted, because all pregnancies are wanted, or
4.   was not wanted?
8.   REFUSED
9.   DON'T KNOW

E80. Which of the following birth control method or methods have you used since [BABY NAME] was born? (CHOOSE ALL THAT APPLY)
INTERVIEWER NOTE: IF R SAYS "YES" TO #1, YOU DO NOT NEED TO READ REMAINING OPTIONS, OTHERWISE READ ALL
IF R IS UNSURE OF IUD TYPE, CHOOSE 'OTHER' AND WRITE 'UNKNOWN IUD'
1.   No form of birth control (GOTO E90)
2.   Contraceptive shot, also called Depo-Provera (GOTO E90)
3.   Combined pill, also known as the regular pill (GOTO E90)
4.   Mini-pill, also known as the progesterone-only pill (GOTO E90)
5.   IUD with hormones or Mirena, also known as the 5-year IUD (PRONOUNCED MER-AYNA)(GOTO E90)
6.   IUD with Copper, also known as the 10-year IUD (GOTO E90)
7.   Condoms (GOTO E90)
8.   OTHER (SPECIFY) (GOTO E81)
88.   REFUSED (GOTO E90)
99.   DON'T KNOW (GOTO E90)

E81.   SPECIFY OTHER
OPEN TEXT [100 CHARACTERS]

E90. Do you have any biological children older than [BABY NAME]?
INTERVIEWER: WE ARE NOT INTERESTED IN FOCUS CHILD'S TWIN.
0.   NO (GOTO F_INTRO)
1.   YES (GOTO E91)
8.   REFUSED (GOTO F_INTRO)
9.   DON'T KNOW (GOTO F_INTRO)

E91.   How old, in months or years and months is the next oldest biological child?
ENTER YEARS

INTERVIEWER: WE ARE NOT INTERESTED IN FOCUS CHILD'S TWIN. IF R 'S ANSWER INDICATES A TWIN/MULTIPLE, GO BACK AND RE-ASK/ENTER E90
_____YEARS [RANGE 0 TO 25 / REFUSED / DON'T KNOW]

E92. HOW OLD, IN MONTHS OR YEARS AND MONTHS IS THE NEXT OLDEST BIOLOGICAL CHILD?
ENTER MONTHS
_____MONTHS [RANGE 0 TO 11 / REFUSED / DON'T KNOW]

F_INTRO   We're almost done. I just have a few final questions that will help us understand what the results mean for our state.

F01.   How old are you?
_____YEARS [RANGE 12 TO 65 / REFUSED]

F10.   Is your total family household income, before taxes, under or over $40,000?
1.   UNDER $40,000 (GOTO F15)
2.   OVER $40,000 (GOTO F20)
3.   EXACTLY $40,000 (GOTO F40)
8.   REFUSED (GOTO F40)
9.   DON'T KNOW (GOTO F40)

F15.   Is your total annual family income under $20,000?
0.   NO (GOTO F40)
1.   YES (GOTO F40)
8.   REFUSED (GOTO F40)
9.   DON'T KNOW (GOTO F40)

F20.   Is your total annual family income over $60,000?
0.   NO (GOTO F40)
1.   YES (GOTO F25)
8.   REFUSED (GOTO F40)
9.   DON'T KNOW (GOTO F40)

F25.   Is your total annual family income over $80,000?
0.   NO (GOTO F40)
1.   YES (GOTO F30)
8.   REFUSED (GOTO F40)
9.   DON'T KNOW (GOTO F40)

F30.   Is your total annual family income over $100,000?
0.   NO
1.   YES
8.   REFUSED
9.   DON'T KNOW

F40.   Are you Hispanic or Latino?
0.   NO
1.   YES
8.   REFUSED
9.   DON'T KNOW

F50.   Which one or more of the following would you say is your race?
1.   White (GOTO F60)
2.   Black or African American (GOTO F60)
3.   Asian (GOTO F60)
4.   Native Hawaiian or Pacific Islander (GOTO F60)
5.   American Indian or Alaska Native (GOTO F60)
6.   OTHER (SPECIFY) (GOTO F51)
8.   REFUSED (GOTO F52)
9.   DON'T KNOW (GOTO F52)

F51.   SPECIFY OTHER RACE
OPEN TEXT [50 CHARACTERS]

IF MORE THAN ONE (1-5) OPTION OR 'OTHER', 'REFUSED', OR 'DON'T
KNOW' CHOSEN IN F50, ASK:
F52.   Would you consider yourself white or non-white?
1.   WHITE
2.   NON-WHITE

F60.   What is the highest level of school you've completed so far?
INTERVIEWER: ONLY RECORD COMPLETED DEGREES
1.   BELOW HIGH SCHOOL
2.   HIGH SCHOOL GRADUATE OR GED
3.   COLLEGE DEGREE (ASSOCIATES OR BACHELORS)
4.   GRADUATE DEGREE
8.   REFUSED
9.   DON'T KNOW

F70.   What county was [BABY NAME] born in?
DROP-DOWN MENU OF 100 NC COUNTIES
REFUSED
DON'T KNOW

F80.   What hospital or birth center was [BABY NAME] born in?
DROP-DOWN MENU OF 133 NC HOSPITALS AND BIRTH CENTERS
REFUSED
DON'T KNOW

F81.   SPECIFY OTHER HOSPITAL
OPEN TEXT [50 CHARACTERS]

F90.	Does your household have more than one phone number?
0.	NO (GOTO END_SUR)
1.	YES (GOTO F91)
8.	REFUSED (GOTO END_SUR)
9.	DON'T KNOW (GOTO END_SUR)

F91.	What are these numbers used for? (CHECK ALL THAT APPLY)
1.	CELL PHONE (GOTO END_SUR)
2.	DEDICATED FAX LINE (GOTO END_SUR)
3.	DEDICATED COMPUTER LINE (GOTO END_SUR)
4.	DEDICATED BUSINESS LINE (GOTO END_SUR)
5.	ADDITIONAL HOUSEHOLD NUMBER(S) (GOTO F92)
8.	REFUSED (GOTO END_SUR)
9.	DON'T KNOW (GOTO END_SUR)

F92.	You said your household has phone numbers that are not for cell phones or computer, fax, or business lines. How many of these additional numbers do you have?
_____HOUSEHOLD NUMBERS [RANGE 1 TO 7 / REFUSED / DON'T KNOW]
(IF 1-7, GOTO F92_CHK; IF REFUSED/DON'T KNOW, GOTO END_SUR)

F92_CHK	So, you have [F92 + 1] phone lines reaching your household, including this one, that are not for cell phones or computer, fax, or business lines?

END_SUR	That's the end of our survey. Thank you so much for taking the time to answer our questions. Good bye.

REFERENCES

(1) The optimal duration of exclusive breastfeeding. J Adv Nurs 2001 Aug;35(3):313-315.

(2) Gartner LM, Morton J, Lawrence RA, Naylor AJ, O'Hare D, Schanler RJ, et al. Breastfeeding and the use of human milk. Pediatrics 2005 Feb;115(2):496-506.

(3) Ip S, Chung M, Raman G, Chew P, Magula N, DeVine D, et al. Breastfeeding and maternal and infant health outcomes in developed countries. Evid Rep Technol Assess (Full Rep) 2007 Apr;(153)(153):1-186.

(4) Department of Health and Human Services. Healthy People 2010. 2000;DHHS # 01-50213.

(5) CDC. Breastfeeding Report Card - United States 2012.

(6) Department of Health and Human Services. Healthy People 2020. Friday, October 05, 2012; Available at: http://healthypeople.gov/2020/default.aspx. Accessed 10/10, 2012.

(7) Blaymore Bier JA, Oliver T, Ferguson A, Vohr BR. Human milk reduces outpatient upper respiratory symptoms in premature infants during their first year of life. J Perinatol 2002 Jul-Aug;22(5):354-359.

(8) Dewey KG, Heinig MJ, Nommsen-Rivers LA. Differences in morbidity between breast-fed and formula-fed infants. J Pediatr 1995 May;126(5 Pt 1):696-702.

(9) Duncan B, Ey J, Holberg CJ, Wright AL, Martinez FD, Taussig LM. Exclusive breast-feeding for at least 4 months protects against otitis media. Pediatrics 1993 May;91(5):867-872.

(10) Heinig MJ. Host defense benefits of breastfeeding for the infant. Effect of breastfeeding duration and exclusivity. Pediatr Clin North Am 2001 Feb;48(1):105-23, ix.

(11) Istre GR, Conner JS, Broome CV, Hightower A, Hopkins RS. Risk factors for primary invasive Haemophilus influenzae disease: increased risk from day care attendance and school-aged household members. J Pediatr 1985 Feb;106(2):190-195.

(12) Lucas A, Cole TJ. Breast milk and neonatal necrotising enterocolitis. Lancet 1990 Dec 22-29;336(8730):1519-1523.

(13) Marild S, Hansson S, Jodal U, Oden A, Svedberg K. Protective effect of breastfeeding against urinary tract infection. Acta Paediatr 2004 Feb;93(2):164-168.

(14) Bener A, Denic S, Galadari S. Longer breast-feeding and protection against childhood leukaemia and lymphomas. Eur J Cancer 2001 Jan;37(2):234-238.

(15) Davis MK. Review of the evidence for an association between infant feeding and childhood cancer. Int J Cancer Suppl 1998;11:29-33.

(16) Horne RS, Parslow PM, Ferens D, Watts AM, Adamson TM. Comparison of evoked arousability in breast and formula fed infants. Arch Dis Child 2004 Jan;89(1):22-25.

(17) Kostraba JN, Cruickshanks KJ, Lawler-Heavner J, Jobim LF, Rewers MJ, Gay EC, et al. Early exposure to cow's milk and solid foods in infancy, genetic predisposition, and risk of IDDM. Diabetes 1993 Feb;42(2):288-295.

(18) McVea KL, Turner PD, Peppler DK. The role of breastfeeding in sudden infant death syndrome. J Hum Lact 2000 Feb;16(1):13-20.

(19) Pettitt DJ, Forman MR, Hanson RL, Knowler WC, Bennett PH. Breastfeeding and incidence of non-insulin-dependent diabetes mellitus in Pima Indians. Lancet 1997 Jul 19;350(9072):166-168.

(20) Scragg LK, Mitchell EA, Tonkin SL, Hassall IB. Evaluation of the cot death prevention programme in South Auckland. N Z Med J 1993 Jan 27;106(948):8-10.

(21) Gdalevich M, Mimouni D, Mimouni M. Breast-feeding and the risk of bronchial asthma in childhood: a systematic review with meta-analysis of prospective studies. J Pediatr 2001 Aug;139(2):261-266.

(22) Oddy WH, Peat JK, de Klerk NH. Maternal asthma, infant feeding, and the risk of asthma in childhood. J Allergy Clin Immunol 2002 Jul;110(1):65-67.

(23) Armstrong J, Reilly JJ, Child Health Information Team. Breastfeeding and lowering the risk of childhood obesity. Lancet 2002 Jun 8;359(9322):2003-2004.

(24) Arenz S, Ruckerl R, Koletzko B, von Kries R. Breast-feeding and childhood obesity--a systematic review. Int J Obes Relat Metab Disord 2004 Oct;28(10):1247-1256.

(25) Jacobson SW, Chiodo LM, Jacobson JL. Breastfeeding effects on intelligence quotient in 4- and 11-year-old children. Pediatrics 1999 May;103(5):e71.

(26) Mortensen EL, Michaelsen KF, Sanders SA, Reinisch JM. The association between duration of breastfeeding and adult intelligence. JAMA 2002 May 8;287(18):2365-2371.

(27) Horwood LJ, Fergusson DM. Breastfeeding and later cognitive and academic outcomes. Pediatrics 1998 Jan;101(1):E9.

(28) Labbok MH. Effects of breastfeeding on the mother. Pediatr Clin North Am 2001 Feb;48(1):143-158.

(29) Cumming RG, Klineberg RJ. Breastfeeding and other reproductive factors and the risk of hip fractures in elderly women. Int J Epidemiol 1993 Aug;22(4):684-691.

(30) Enger SM, Ross RK, Paganini-Hill A, Bernstein L. Breastfeeding experience and breast cancer risk among postmenopausal women. Cancer Epidemiol Biomarkers Prev 1998 May;7(5):365-369.

(31) Lopez JM, Gonzalez G, Reyes V, Campino C, Diaz S. Bone turnover and density in healthy women during breastfeeding and after weaning. Osteoporos Int 1996;6(2):153-159.

(32) Newcomb PA, Storer BE, Longnecker MP, Mittendorf R, Greenberg ER, Clapp RW, et al. Lactation and a reduced risk of premenopausal breast cancer. N Engl J Med 1994 Jan 13;330(2):81-87.

(33) Rosenblatt KA, Thomas DB. Lactation and the risk of epithelial ovarian cancer. The WHO Collaborative Study of Neoplasia and Steroid Contraceptives. Int J Epidemiol 1993 Apr;22(2):192-197.

(34) Ball TM, Wright AL. Health care costs of formula-feeding in the first year of life. Pediatrics 1999 Apr;103(4 Pt 2):870-876.

(35) Bartick M, Reinhold A. The burden of suboptimal breastfeeding in the United States: a pediatric cost analysis. Pediatrics 2010 May;125(5):e1048-56.

(36) Gillespie D, Maguire ES, Neuse M, Sinding SW, Speidel JJ. International family-planning budgets in the "new US" era. Lancet 2009 May 2;373(9674):1505-1507.

(37) Speidel JJ, Sinding S, Gillespie D, Maguire E, Neuse M. Making the Case for US International family planning assistance. Available at: http://www.jhsph.edu/research/centers-and-institutes/bill-and-melinda-gates-institute-for-population-and-reproductive-health/policy_practice/publications/index.html. Accessed 10/10, 2012.

(38) CDC. From the Centers for Disease Control and Prevention. Achievements in public health, 1900-1999: family planning. JAMA 2000 Jan 19;283(3):326-7, 331.

(39) Finer LB, Henshaw SK. Disparities in rates of unintended pregnancy in the United States, 1994 and 2001. Perspect Sex Reprod Health 2006 Jun;38(2):90-96.

(40) Mosher WD, Jones J. Use of contraception in the United States: 1982-2008. Vital Health Stat 23 2010 Aug;(29)(29):1-44.

(41) Trussell J, Henry N, Hassan F, Prezioso A, Law A, Filonenko A. Burden of unintended pregnancy in the United States: potential savings with increased use of long-acting reversible contraception. Contraception 2012 Sep 6.

(42) Truitt ST, Fraser AB, Grimes DA, Gallo MF, Schulz KF. Combined hormonal versus nonhormonal versus progestin-only contraception in lactation. Cochrane Database Syst Rev 2003;(2)(2):CD003988.

(43) Conde-Agudelo A, Belizan JM. Maternal morbidity and mortality associated with interpregnancy interval: cross sectional study. BMJ 2000 Nov 18;321(7271):1255-1259.

(44) Shipp TD, Zelop CM, Repke JT, Cohen A, Lieberman E. Interdelivery interval and risk of symptomatic uterine rupture. Obstet Gynecol 2001 Feb;97(2):175-177.

(45) Hight-Laukaran V, Labbok MH, Peterson AE, Fletcher V, von Hertzen H, Van Look PF. Multicenter study of the Lactational Amenorrhea Method (LAM): II. Acceptability, utility, and policy implications. Contraception 1997 Jun;55(6):337-346.

(46) Labbok MH, Hight-Laukaran V, Peterson AE, Fletcher V, von Hertzen H, Van Look PF. Multicenter study of the Lactational Amenorrhea Method (LAM): I. Efficacy, duration, and implications for clinical application. Contraception 1997 Jun;55(6):327-336.

(47) Kennedy KI, Visness CM. Contraceptive efficacy of lactational amenorrhoea. Lancet 1992 Jan 25;339(8787):227-230.

(48) Hale TW, Hartmann P editors. Textbook of Human Lactation. First ed. Amarillo, Texas: Hale Publishing; 2007.

(49) Riordan J, Wambach K. Breastfeeding and Human Lactation. Fourth ed. Sudbury, MA: Jones and Bartlett Publishers, LLC; 2010.

(50) Lawrence RA, Lawrence RM. Breastfeeding: A Guide for the Medical Professional. Sixth ed. Philadelphia, PA: Elsevier Mosby; 2005.

(51) Czank C, Henderson J, Kent J, Lai C, Hartmann P. Hormonal Control of the Lactation Cycle. In: Hale T, Hartmann P, editors. Textbook of Human Lactation. First ed.: Hale Publishing, L.P.; 2007. p. 89.

(52) Cregan MD, Hartmann PE. Computerized breast measurement from conception to weaning: clinical implications. J Hum Lact 1999 Jun;15(2):89-96.

(53) Cox DB, Kent JC, Casey TM, Owens RA, Hartmann PE. Breast growth and the urinary excretion of lactose during human pregnancy and early lactation: endocrine relationships. Exp Physiol 1999 Mar;84(2):421-434.

(54) Tyson JE, Hwang P, Guyda H, Friesen HG. Studies of prolactin secretion in human pregnancy. Am J Obstet Gynecol 1972 May 1;113(1):14-20.

(55) Hartmann PE, Trevethan P, Shelton JN. Progesterone and oestrogen and the initiation of lactation in ewes. J Endocrinol 1973 Nov;59(2):249-259.

(56) Kuhn NJ. Progesterone withdrawal as the lactogenic trigger in the rat. J Endocr 1969 Sep;44:39-54.

(57) Turkington RW, Hill RL. Lactose synthetase: progesterone inhibition of the induction of alpha-lactalbumin. Science 1969 Mar 28;163(3874):1458-1460.

(58) Neifert MR, McDonough SL, Neville MC. Failure of lactogenesis associated with placental retention. Am J Obstet Gynecol 1981 Jun 15;140(4):477-478.

(59) Nguyen DA, Parlow AF, Neville MC. Hormonal regulation of tight junction closure in the mouse mammary epithelium during the transition from pregnancy to lactation. J Endocrinol 2001 Aug;170(2):347-356.

(60) Neville MC, Allen JC, Archer PC, Casey CE, Seacat J, Keller RP, et al. Studies in human lactation: milk volume and nutrient composition during weaning and lactogenesis. Am J Clin Nutr 1991 Jul;54(1):81-92.

(61) Saint L, Smith M, Hartmann PE. The yield and nutrient content of colostrum and milk of women from giving birth to 1 month post-partum. Br J Nutr 1984 Jul;52(1):87-95.

(62) Madden JD, Boyar RM, MacDonald PC, Porter JC. Analysis of secretory patterns of prolactin and gonadotropins during twenty-four hours in a lactating woman before and after resumption of menses. Am J Obstet Gynecol 1978 Oct 15;132(4):436-441.

(63) Kenyon CAP. Hormone Levels During Pregnancy. Available at: http://www.flyfishingdevon.co.uk/salmon/year2/psy221maternal_behaviour/maternal_behaviour.htm. Accessed 10/10, 2012.

(64) Neville MC, Morton J. Physiology and endocrine changes underlying human lactogenesis II. J Nutr 2001 Nov;131(11):3005S-8S.

(65) Kulski JK, Hartmann PE. Changes in human milk composition during the initiation of lactation. Aust J Exp Biol Med Sci 1981 Feb;59(1):101-114.

(66) Neville MC, McFadden TB, Forsyth I. Hormonal regulation of mammary differentiation and milk secretion. J Mammary Gland Biol Neoplasia 2002 Jan;7(1):49-66.

(67) Chao S. The effect of lactation on ovulation and fertility. Clin Perinatol 1987 Mar;14(1):39-50.

(68) Noel GL, Suh HK, Frantz AG. Prolactin release during nursing and breast stimulation in postpartum and nonpostpartum subjects. J Clin Endocrinol Metab 1974 Mar;38(3):413-423.

(69) Neville MC. Anatomy and physiology of lactation. Pediatr Clin North Am 2001 Feb;48(1):13-34.

(70) Battin DA, Marrs RP, Fleiss PM, Mishell DR,Jr. Effect of suckling on serum prolactin, luteinizing hormone, follicle-stimulating hormone, and estradiol during prolonged lactation. Obstet Gynecol 1985 Jun;65(6):785-788.

(71) Cox DB, Owens RA, Hartmann PE. Blood and milk prolactin and the rate of milk synthesis in women. Exp Physiol 1996 Nov;81(6):1007-1020.

(72) Tay CC, Glasier AF, McNeilly AS. Twenty-four hour patterns of prolactin secretion during lactation and the relationship to suckling and the resumption of fertility in breast-feeding women. Hum Reprod 1996 May;11(5):950-955.

(73) Groer MW. Differences between exclusive breastfeeders, formula-feeders, and controls: a study of stress, mood, and endocrine variables. Biol Res Nurs 2005 Oct;7(2):106-117.

(74) Baron JA, Bulbrook RD, Wang DY, Kwa HG. Cigarette smoking and prolactin in women. Br Med J (Clin Res Ed) 1986 Aug 23;293(6545):482-483.

(75) Stallings JF, Worthman CM, Panter-Brick C, Coates RJ. Prolactin response to suckling and maintenance of postpartum amenorrhea among intensively breastfeeding Nepali women. Endocr Res 1996 Feb;22(1):1-28.

(76) Ostrom KM. A review of the hormone prolactin during lactation. Prog Food Nutr Sci 1990;14(1):1-43.

(77) Zuppa AA, Tornesello A, Papacci P, Tortorolo G, Segni G, Lafuenti G, et al. Relationship between maternal parity, basal prolactin levels and neonatal breast milk intake. Biol Neonate 1988;53(3):144-147.

(78) Hill PD, Chatterton RT,Jr, Aldag JC. Serum prolactin in breastfeeding: state of the science. Biol Res Nurs 1999 Jul;1(1):65-75.

(79) Ueda T, Yokoyama Y, Irahara M, Aono T. Influence of psychological stress on suckling-induced pulsatile oxytocin release. Obstet Gynecol 1994 Aug;84(2):259-262.

(80) Djiane J, Durand P. Prolactin-progesterone antagonism in self regulation of prolactin receptors in the mammary gland. Nature 1977 Apr 14;266(5603):641-643.

(81) Tucker HA. Hormones, mammary growth, and lactation: a 41-year perspective. J Dairy Sci 2000 Apr;83(4):874-884.

(82) Nguyen DA, Neville MC. Tight junction regulation in the mammary gland. J Mammary Gland Biol Neoplasia 1998 Jul;3(3):233-246.

(83) Berg MN, Dharmarajan AM, Waddell BJ. Glucocorticoids and progesterone prevent apoptosis in the lactating rat mammary gland. Endocrinology 2002 Jan;143(1):222-227.

(84) Feng Z, Marti A, Jehn B, Altermatt HJ, Chicaiza G, Jaggi R. Glucocorticoid and progesterone inhibit involution and programmed cell death in the mouse mammary gland. J Cell Biol 1995 Nov;131(4):1095-1103.

(85) Rosen JM, Wyszomierski SL, Hadsell D. Regulation of milk protein gene expression. Annu Rev Nutr 1999;19:407-436.

(86) Stocklin E, Wissler M, Gouilleux F, Groner B. Functional interactions between Stat5 and the glucocorticoid receptor. Nature 1996 Oct 24;383(6602):726-728.

(87) Stoecklin E, Wissler M, Moriggl R, Groner B. Specific DNA binding of Stat5, but not of glucocorticoid receptor, is required for their functional cooperation in the regulation of gene transcription. Mol Cell Biol 1997 Nov;17(11):6708-6716.

(88) Collier RJ, Tucker HA. Regulation of cortisol uptake in mammary tissue of cows. J Dairy Sci 1978 Dec;61(12):1709-1714.

(89) Maki M, Hirose M, Chiba H. Occurrence of common binding sites for progestin and glucocorticoid in the lactating mammary gland of the rat. J Biochem 1980 Dec;88(6):1845-1854.

(90) Mesiano S. Roles of estrogen and progesterone in human parturition. Front Horm Res 2001;27:86-104.

(91) Booker DE, Pahl IR, Forbes DA. Control of postpartum breast engorgement with oral contraceptives. II. Am J Obstet Gynecol 1970 Sep 15;108(2):240-242.

(92) Gambrell RD,Jr. Immediate postpartum oral contraception. Obstet Gynecol 1970 Jul;36(1):101-106.

(93) Tankeyoon M, Dusitsin N, Chalapati S, Koetsawang S, Saibiang S, Sas M, et al. Effects of hormonal contraceptives on milk volume and infant growth. WHO Special Programme of Research, Development and Research Training in Human Reproduction Task force on oral contraceptives. Contraception 1984 Dec;30(6):505-522.

(94) Treffers PE. Breastfeeding and contraception. Ned Tijdschr Geneeskd 1999 Sep 18;143(38):1900-1904.

(95) Booker DE, Pahl IR. Control of postpartum breast engorgement with oral contraceptives. Am J Obstet Gynecol 1967 Aug 15;98(8):1099-1101.

(96) Raymond V, Beaulieu M, Labrie F, Boissier J. Potent antidopaminergic activity of estradiol at the pituitary level on prolactin release. Science 1978 Jun 9;200(4346):1173-1175.

(97) Ek CJ, Dziegielewska KM, Habgood MD, Saunders NR. Barriers in the developing brain and Neurotoxicology. Neurotoxicology 2012 Jun;33(3):586-604.

(98) World Health Organization. Medical eligibility criteria for contraceptive use. 2009.

(99) Centers for Disease Control and Prevention (CDC). U S. Medical Eligibility Criteria for Contraceptive Use, 2010. MMWR Recomm Rep 2010 Jun 18;59(RR-4):1-86.

(100) Curtis KM, Jamieson DJ, Peterson HB, Marchbanks PA. Adaptation of the World Health Organization's medical eligibility criteria for contraceptive use for use in the United States. Contraception 2010 Jul;82(1):3-9.

(101) Jacobson JC, Aikins Murphy P. United States medical eligibility criteria for contraceptive use 2010: a review of changes. J Midwifery Womens Health 2011 Nov-Dec;56(6):598-607.

(102) Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. U.s. Selected practice recommendations for contraceptive use, 2013: adapted from the world health organization selected practice recommendations for contraceptive use, 2nd edition. MMWR Recomm Rep 2013 Jun 21;62(RR-05):1-60.

(103) Lawrence RA. Challenges to successful breastfeeding. Breastfeed Med 2012 Feb;7(1):1-2.

(104) Kapp N, Curtis KM. Combined oral contraceptive use among breastfeeding women: a systematic review. Contraception 2010 Jul;82(1):10-16.

(105) Kapp N, Curtis K, Nanda K. Progestogen-only contraceptive use among breastfeeding women: a systematic review. Contraception 2010 Jul;82(1):17-37.

(106) Nath A, Sitruk-Ware R. Progesterone vaginal ring for contraceptive use during lactation. Contraception 2010 Nov;82(5):428-434.

(107) Brownell EA, Fernandez ID, Howard CR, Fisher SG, Ternullo SR, Buckley RJ, et al. A systematic review of early postpartum medroxyprogesterone receipt and early

breastfeeding cessation: evaluating the methodological rigor of the evidence. Breastfeed Med 2012 Feb;7(1):10-18.

(108) Erwin PC. To use or not use combined hormonal oral contraceptives during lactation. Fam Plann Perspect 1994 Jan-Feb;26(1):26-30, 33.

(109) Croxatto HB, Diaz S, Peralta O, Juez G, Herreros C, Casado ME, et al. Fertility regulation in nursing women: IV. Long-term influence of a low-dose combined oral contraceptive initiated at day 30 postpartum upon lactation and infant growth. Contraception 1983 Jan;27(1):13-25.

(110) Diaz S, Peralta O, Juez G, Herreros C, Casado ME, Salvatierra AM, et al. Fertility regulation in nursing women: III. Short-term influence of a low-dose combined oral contraceptive upon lactation and infant growth. Contraception 1983 Jan;27(1):1-11.

(111) WHO. Effects of hormonal contraceptives on breast milk composition and infant growth. World Health Organization (WHO) Task Force on Oral Contraceptives. Stud Fam Plann 1988 Nov-Dec;19(6 Pt 1):361-369.

(112) Nilsson S, Mellbin T, Hofvander Y, Sundelin C, Valentin J, Nygren KG. Long-term follow-up of children breast-fed by mothers using oral contraceptives. Contraception 1986 Nov;34(5):443-457.

(113) Peralta O, Diaz S, Juez G, Herreros C, Casado ME, Salvatierra AM, et al. Fertility regulation in nursing women: V. Long-term influence of a low-dose combined oral contraceptive initiated at day 90 postpartum upon lactation and infant growth. Contraception 1983 Jan;27(1):27-38.

(114) Diaz S, Zepeda A, Maturana X, Reyes MV, Miranda P, Casado ME, et al. Fertility regulation in nursing women. IX. Contraceptive performance, duration of lactation, infant growth, and bleeding patterns during use of progesterone vaginal rings, progestin-only pills, Norplant implants, and Copper T 380-A intrauterine devices. Contraception 1997 Oct;56(4):223-232.

(115) Massai R, Miranda P, Valdes P, Lavin P, Zepeda A, Casado ME, et al. Preregistration study on the safety and contraceptive efficacy of a progesterone-releasing vaginal ring in Chilean nursing women. Contraception 1999 Jul;60(1):9-14.

(116) Massai R, Quinteros E, Reyes MV, Caviedes R, Zepeda A, Montero JC, et al. Extended use of a progesterone-releasing vaginal ring in nursing women: a phase II clinical trial. Contraception 2005 Nov;72(5):352-357.

(117) Shaaban MM. Contraception with progestogens and progesterone during lactation. J Steroid Biochem Mol Biol 1991;40(4-6):705-710.

(118) Sivin I, Diaz S, Croxatto HB, Miranda P, Shaaban M, Sayed EH, et al. Contraceptives for lactating women: a comparative trial of a progesterone-releasing vaginal ring and the copper T 380A IUD. Contraception 1997 Apr;55(4):225-232.

(119) WHO. Combined hormonal contraceptive use during the postpartum period. 2010.

(120) Shaamash AH, Sayed GH, Hussien MM, Shaaban MM. A comparative study of the levonorgestrel-releasing intrauterine system Mirena versus the Copper T380A intrauterine device during lactation: breast-feeding performance, infant growth and infant development. Contraception 2005 Nov;72(5):346-351.

(121) Khella AK, Fahim HI, Issa AH, Sokal DC, Gadalla MA. Lactational amenorrhea as a method of family planning in Egypt. Contraception 2004 Apr;69(4):317-322.

(122) Heikkila M, Luukkainen T. Duration of breast-feeding and development of children after insertion of a levonorgestrel-releasing intrauterine contraceptive device. Contraception 1982 Mar;25(3):279-292.

(123) Seth U, Yadava HS, Agarwal N, Laumas KR, Hingorani V. Effect of a subdermal silastic implant containing norethindrone acetate on human lactation. Contraception 1977 Oct;16(4):383-398.

(124) Brito MB, Ferriani RA, Quintana SM, Yazlle ME, Silva de Sa MF, Vieira CS. Safety of the etonogestrel-releasing implant during the immediate postpartum period: a pilot study. Contraception 2009 Dec;80(6):519-526.

(125) Gurtcheff SE, Turok DK, Stoddard G, Murphy PA, Gibson M, Jones KP. Lactogenesis after early postpartum use of the contraceptive implant: a randomized controlled trial. Obstet Gynecol 2011 May;117(5):1114-1121.

(126) Abdulla KA, Elwan SI, Salem HS, Shaaban MM. Effect of early postpartum use of the contraceptive implants, NORPLANT, on the serum levels of immunoglobulins of the mothers and their breastfed infants. Contraception 1985 Sep;32(3):261-266.

(127) Abdel-Aleem H, Abol-Oyoun el-S M, Shaaban MM, el-Saeed M, Shoukry M, Makhlouf A, et al. The use of nomegestrol acetate subdermal contraceptive implant, uniplant, during lactation. Contraception 1996 Nov;54(5):281-286.

(128) Croxatto HB, Diaz S, Peralta O, Juez G, Casado ME, Salvatierra AM, et al. Fertility regulation in nursing women. II. Comparative performance of progesterone implants versus placebo and copper T. Am J Obstet Gynecol 1982 Sep 15;144(2):201-208.

(129) Diaz S, Peralta O, Juez G, Herreros C, Casado ME, Salvatierra AM, et al. Fertility regulation in nursing women. VI. Contraceptive effectiveness of a subdermal progesterone implant. Contraception 1984 Oct;30(4):311-325.

(130) Diaz S, Herreros C, Juez G, Casado ME, Salvatierra AM, Miranda P, et al. Fertility regulation in nursing women: VII. Influence of NORPLANT levonorgestrel implants upon lactation and infant growth. Contraception 1985 Jul;32(1):53-74.

(131) Massai MR, Diaz S, Quinteros E, Reyes MV, Herreros C, Zepeda A, et al. Contraceptive efficacy and clinical performance of Nestorone implants in postpartum women. Contraception 2001 Dec;64(6):369-376.

(132) Taneepanichskul S, Reinprayoon D, Thaithumyanon P, Praisuwanna P, Tosukhowong P, Dieben T. Effects of the etonogestrel-releasing implant Implanon and a nonmedicated intrauterine device on the growth of breast-fed infants. Contraception 2006 Apr;73(4):368-371.

(133) Reinprayoon D, Taneepanichskul S, Bunyavejchevin S, Thaithumyanon P, Punnahitananda S, Tosukhowong P, et al. Effects of the etonogestrel-releasing contraceptive implant (Implanon on parameters of breastfeeding compared to those of an intrauterine device. Contraception 2000 Nov;62(5):239-246.

(134) Schiappacasse V, Diaz S, Zepeda A, Alvarado R, Herreros C. Health and growth of infants breastfed by Norplant contraceptive implants users: a six-year follow-up study. Contraception 2002 Jul;66(1):57-65.

(135) Shaaban MM, Salem HT, Abdullah KA. Influence of levonorgestrel contraceptive implants, NORPLANT, initiated early postpartum upon lactation and infant growth. Contraception 1985 Dec;32(6):623-635.

(136) Shikary ZK, Betrabet SS, Toddywala WS, Patel DM, Datey S, Saxena BN. Pharmacodynamic effects of levonorgestrel (LNG) administered either orally or subdermally to early postpartum lactating mothers on the urinary levels of follicle stimulating hormone (FSH), luteinizing hormone (LH) and testosterone (T) in their breast-fed male infants. Contraception 1986 Oct;34(4):403-412.

(137) WHO. Progestogen-only contraceptives during lactation: II. Infant development. World Health Organization, Task Force for Epidemiological Research on Reproductive Health; Special Programme of Research, Development, and Research Training in Human Reproduction. Contraception 1994 Jul;50(1):55-68.

(138) WHO. Progestogen-only contraceptives during lactation: I. Infant growth. World Health Organization Task force for Epidemiological Research on Reproductive Health; Special Programme of Research, Development and Research Training in Human Reproduction. Contraception 1994 Jul;50(1):35-53.

(139) Affandi B, Karmadibrata S, Prihartono J, Lubis F, Samil RS. Effect of Norplant on mothers and infants in the postpartum period. Adv Contracept 1986 Dec;2(4):371-380.

(140) Coutinho EM, Athayde C, Dantas C, Hirsch C, Barbosa I. Use of a single implant of elcometrine (ST-1435), a nonorally active progestin, as a long acting contraceptive for postpartum nursing women. Contraception 1999 Feb;59(2):115-122.

(141) Hannon PR, Duggan AK, Serwint JR, Vogelhut JW, Witter F, DeAngelis C. The influence of medroxyprogesterone on the duration of breast-feeding in mothers in an urban community. Arch Pediatr Adolesc Med 1997 May;151(5):490-496.

(142) Halderman LD, Nelson AL. Impact of early postpartum administration of progestin-only hormonal contraceptives compared with nonhormonal contraceptives on short-term breast-feeding patterns. Am J Obstet Gynecol 2002 Jun;186(6):1250-6; discussion 1256-8.

(143) Lawrie TA, Hofmeyr GJ, De Jager M, Berk M, Paiker J, Viljoen E. A double-blind randomised placebo controlled trial of postnatal norethisterone enanthate: the effect on postnatal depression and serum hormones. Br J Obstet Gynaecol 1998 Oct;105(10):1082-1090.

(144) Guiloff E, Ibarra-Polo A, Zanartu J, Toscanini C, Mischler TW, Gomez-Rogers C. Effect of contraception on lactation. Am J Obstet Gynecol 1974 Jan 1;118(1):42-45.

(145) Karim M, Ammar R, el-Mahgoub S, el-Ganzoury B, Fikri F, Abdou I. Injected progestogen and lactation. Br Med J 1971 Jan 23;1(5742):200-203.

(146) Jimenez J, Ochoa M, Soler MP, Portales P. Long-term follow-up of children breast-fed by mothers receiving depot-medroxyprogesterone acetate. Contraception 1984 Dec;30(6):523-533.

(147) Zacharias S, Aguilera E, Assenzo JR, Zanartu J. Effects of hormonal and nonhormonal contraceptives on lactation and incidence of pregnancy. Contraception 1986 Mar;33(3):203-213.

(148) Baheiraei A, Ardsetani N, Ghazizadeh S. Effects of progestogen-only contraceptives on breast-feeding and infant growth. Int J Gynaecol Obstet 2001 Aug;74(2):203-205.

(149) McEwan JA, Joyce DN, Tothill AU, Hawkins DF. Early experience in contraception with a new progestogen. Contraception 1977 Oct;16(4):339-350.

(150) Zanartu J, Aguilera E, Munoz-Pinto G. Maintenance of lactation by means of continuous low-dose progestogen given post-partum as a contraceptive. Contraception 1976 Mar;13(3):313-318.

(151) Kamal I, Hefnawi F, Ghoneim M, Abdallah M, Abdel Razek S. Clinical, biochemical, and experimental studies on lactation. V. Clinical effects of steroids on the initiation of lactation. Am J Obstet Gynecol 1970 Oct 15;108(4):655-658.

(152) McCann MF, Moggia AV, Higgins JE, Potts M, Becker C. The effects of a progestin-only oral contraceptive (levonorgestrel 0.03 mg) on breast-feeding. Contraception 1989 Dec;40(6):635-648.

(153) Giner Velazquez J, Cortes Gallegos V, Sotelo Lopez A, Bondani G. Effect of daily oral administration of 0.350 mg of norethindrone on lactation and on the composition of milk. Ginecol Obstet Mex 1976 Jul;40(237):31-39.

(154) West CP. The acceptability of a progestagen-only contraceptive during breast-feeding. Contraception 1983 Jun;27(6):563-569.

(155) Bjarnadottir RI, Gottfredsdottir H, Sigurdardottir K, Geirsson RT, Dieben TO. Comparative study of the effects of a progestogen-only pill containing desogestrel and an intrauterine contraceptive device in lactating women. BJOG 2001 Nov;108(11):1174-1180.

(156) Pippins JR, Brawarsky P, Jackson RA, Fuentes-Afflick E, Haas JS. Association of breastfeeding with maternal depressive symptoms. J Womens Health (Larchmt) 2006 Jul-Aug;15(6):754-762.

(157) McDonald SD, Pullenayegum E, Chapman B, Vera C, Giglia L, Fusch C, et al. Prevalence and predictors of exclusive breastfeeding at hospital discharge. Obstet Gynecol 2012 Jun;119(6):1171-1179.

(158) Geraghty S, Davidson B, Tabangin M, Morrow A. Predictors of breastmilk expression by 1 month postpartum and influence on breastmilk feeding duration. Breastfeed Med 2012 Apr;7(2):112-117.

(159) Bogen DL, Hanusa BH, Moses-Kolko E, Wisner KL. Are maternal depression or symptom severity associated with breastfeeding intention or outcomes? J Clin Psychiatry 2010 Aug;71(8):1069-1078.

(160) Singh GK, Kogan MD, Dee DL. Nativity/immigrant status, race/ethnicity, and socioeconomic determinants of breastfeeding initiation and duration in the United States, 2003. Pediatrics 2007 Feb;119 Suppl 1:S38-46.

(161) Flower KB, Willoughby M, Cadigan RJ, Perrin EM, Randolph G, Family Life Project Investigative Team. Understanding breastfeeding initiation and continuation in rural communities: a combined qualitative/quantitative approach. Matern Child Health J 2008 May;12(3):402-414.

(162) Kehler HL, Chaput KH, Tough SC. Risk factors for cessation of breastfeeding prior to six months postpartum among a community sample of women in Calgary, Alberta. Can J Public Health 2009 2009;100(5):376-380.

(163) Taveras EM, Capra AM, Braveman PA, Jensvold NG, Escobar GJ, Lieu TA. Clinician support and psychosocial risk factors associated with breastfeeding discontinuation. Pediatrics 2003 Jul;112(1 Pt 1):108-115.

(164) Belanoff CM, McManus BM, Carle AC, McCormick MC, Subramanian SV. Racial/ethnic variation in breastfeeding across the US: a multilevel analysis from the National Survey of Children's Health, 2007. Matern Child Health J 2012 Apr;16 Suppl 1:S14-26.

(165) Liu J, Smith MG, Dobre MA, Ferguson JE. Maternal obesity and breast-feeding practices among white and black women. Obesity (Silver Spring) 2010 Jan;18(1):175-182.

(166) Gill SL. Breastfeeding by Hispanic women. Journal of obstetric, gynecologic, and neonatal nursing : JOGNN / NAACOG JID - 8503123 0707.

(167) Soni S, Gupta A, Jacobs AJ. Exclusive breastfeeding rates in a multiethnic population at a community hospital. J Reprod Med 2011 May-Jun;56(5-6):195-198.

(168) Centers for Disease Control and Prevention. Breastfeeding among U.S. children born 2000–2009,
 CDC National Immunization Survey. August 1, 2012; Available at: http://www.cdc.gov/breastfeeding/data/NIS_data/2007/map_1.htm. Accessed 06/10, 2013.

(169) Chapman DJ, Perez-Escamilla R. Maternal perception of the onset of lactation is a valid, public health indicator of lactogenesis stage II. J Nutr 2000 Dec;130(12):2972-2980.

(170) Kitsantas P, Gaffney KF, Kornides ML. Prepregnancy body mass index, socioeconomic status, race/ethnicity and breastfeeding practices. J Perinat Med 2011 Nov 2;40(1):77-83.

(171) Hilson JA, Rasmussen KM, Kjolhede CL. High prepregnant body mass index is associated with poor lactation outcomes among white, rural women independent of psychosocial and demographic correlates. J Hum Lact 2004 Feb;20(1):18-29.

(172) Li R, Ogden C, Ballew C, Gillespie C, Grummer-Strawn L. Prevalence of exclusive breastfeeding among US infants: the Third National Health and Nutrition Examination Survey (Phase II, 1991-1994). Am J Public Health 2002 Jul;92(7):1107-1110.

(173) Li R, Jewell S, Grummer-Strawn L. Maternal obesity and breast-feeding practices. Am J Clin Nutr 2003 Apr;77(4):931-936.

(174) Kugyelka JG, Rasmussen KM, Frongillo EA. Maternal obesity is negatively associated with breastfeeding success among Hispanic but not Black women. J Nutr 2004 Jul;134(7):1746-1753.

(175) Hilson JA, Rasmussen KM, Kjolhede CL. Excessive weight gain during pregnancy is associated with earlier termination of breast-feeding among White women. J Nutr 2006 Jan;136(1):140-146.

(176) Entwistle F, Kendall S, Mead M. Breastfeeding support - the importance of self-efficacy for low-income women. Matern Child Nutr 2010 Jul 1;6(3):228-242.

(177) Dunn S, Davies B, McCleary L, Edwards N, Gaboury I. The relationship between vulnerability factors and breastfeeding outcome. J Obstet Gynecol Neonatal Nurs 2006 Jan-Feb;35(1):87-97.

(178) Wolfberg AJ, Michels KB, Shields W, O'Campo P, Bronner Y, Bienstock J. Dads as breastfeeding advocates: results from a randomized controlled trial of an educational intervention. Am J Obstet Gynecol 2004 Sep;191(3):708-712.

(179) Shapiro-Mendoza C, Selwyn BJ, Smith DP, Sanderson M. Parental pregnancy intention and early childhood stunting: findings from Bolivia. Int J Epidemiol 2005 Apr;34(2):387-396.

(180) Marston C, Cleland J. Do unintended pregnancies carried to term lead to adverse outcomes for mother and child? An assessment in five developing countries. Popul Stud (Camb) 2003;57(1):77-93.

(181) David HP. Born unwanted: mental health costs and consequences. Am J Orthopsychiatry 2011 Apr;81(2):184-192.

(182) Taylor JS, Cabral HJ. Are women with an unintended pregnancy less likely to breastfeed? J Fam Pract 2002 May;51(5):431-436.

(183) Chapman DJ, Morel K, Bermudez-Millan A, Young S, Damio G, Perez-Escamilla R. Breastfeeding education and support trial for overweight and obese women: a randomized trial. Pediatrics 2013 Jan;131(1):e162-70.

(184) Bunik M, Shobe P, O'Connor ME, Beaty B, Langendoerfer S, Crane L, et al. Are 2 weeks of daily breastfeeding support insufficient to overcome the influences of formula? Acad Pediatr 2010 Jan-Feb;10(1):21-28.

(185) Kramer MS, Barr RG, Dagenais S, Yang H, Jones P, Ciofani L, et al. Pacifier use, early weaning, and cry/fuss behavior: a randomized controlled trial. JAMA 2001 Jul 18;286(3):322-326.

(186) Chapman DJ, Damio G, Young S, Perez-Escamilla R. Effectiveness of breastfeeding peer counseling in a low-income, predominantly Latina population: a randomized controlled trial. Arch Pediatr Adolesc Med 2004 Sep;158(9):897-902.

(187) Petrova A, Ayers C, Stechna S, Gerling JA, Mehta R. Effectiveness of exclusive breastfeeding promotion in low-income mothers: a randomized controlled study. Breastfeed Med 2009 Jun;4(2):63-69.

(188) Wambach KA, Aaronson L, Breedlove G, Domian EW, Rojjanasrirat W, Yeh HW. A randomized controlled trial of breastfeeding support and education for adolescent mothers. West J Nurs Res 2011 Jun;33(4):486-505.

(189) Pugh LC, Milligan RA, Frick KD, Spatz D, Bronner Y. Breastfeeding duration, costs, and benefits of a support program for low-income breastfeeding women. Birth 2002 Jun;29(2):95-100.

(190) Anderson AK, Damio G, Young S, Chapman DJ, Perez-Escamilla R. A randomized trial assessing the efficacy of peer counseling on exclusive breastfeeding in a predominantly Latina low-income community. Arch Pediatr Adolesc Med 2005 Sep;159(9):836-841.

(191) Bonuck KA, Trombley M, Freeman K, McKee D. Randomized, controlled trial of a prenatal and postnatal lactation consultant intervention on duration and intensity of breastfeeding up to 12 months. Pediatrics 2005 Dec;116(6):1413-1426.

(192) Bonuck KA, Freeman K, Trombley M. Randomized controlled trial of a prenatal and postnatal lactation consultant intervention on infant health care use. Arch Pediatr Adolesc Med 2006 Sep;160(9):953-960.

(193) Chaudron LH, Klein MH, Remington P, Palta M, Allen C, Essex MJ. Predictors, prodromes and incidence of postpartum depression. J Psychosom Obstet Gynaecol 2001 Jun;22(2):103-112.

(194) Groer MW, Morgan K. Immune, health and endocrine characteristics of depressed postpartum mothers. Psychoneuroendocrinology 2007 Feb;32(2):133-139.

(195) McLearn KT, Minkovitz CS, Strobino DM, Marks E, Hou W. Maternal depressive symptoms at 2 to 4 months post partum and early parenting practices. Arch Pediatr Adolesc Med 2006 Mar;160(3):279-284.

(196) Ramsay M, Gisel EG, McCusker J, Bellavance F, Platt R. Infant sucking ability, non-organic failure to thrive, maternal characteristics, and feeding practices: a prospective cohort study. Dev Med Child Neurol 2002 Jun;44(6):405-414.

(197) Dennis CL, McQueen K. Does maternal postpartum depressive symptomatology influence infant feeding outcomes? Acta Paediatr 2007 Apr;96(4):590-594.

(198) Protecting, promoting and supporting breastfeeding: the special role of maternity services. A joint WHO/UNICEF statement. International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics JID - 0210174 0713.

(199) Kramer MS, Chalmers B, Hodnett ED, Sevkovskaya Z, Dzikovich I, Shapiro S, et al. Promotion of Breastfeeding Intervention Trial (PROBIT): a randomized trial in the Republic of Belarus. JAMA 2001 Jan 24-31;285(4):413-420.

(200) Declercq E, Labbok MH, Sakala C, O'Hara M. Hospital practices and women's likelihood of fulfilling their intention to exclusively breastfeed. Am J Public Health 2009 May;99(5):929-935.

(201) DiGirolamo AM, Grummer-Strawn LM, Fein SB. Effect of maternity-care practices on breastfeeding. Pediatrics 2008 Oct;122 Suppl 2:S43-9.

(202) Nickel NC, Labbok MH, Hudgens MG, Daniels JL. The extent that noncompliance with the ten steps to successful breastfeeding influences breastfeeding duration. J Hum Lact 2013 Feb;29(1):59-70.

(203) Colaizy TT, Saftlas AF, Morriss FH,Jr. Maternal intention to breast-feed and breast-feeding outcomes in term and preterm infants: Pregnancy Risk Assessment Monitoring System (PRAMS), 2000-2003. Public Health Nutr 2012 Apr;15(4):702-710.

(204) Taylor JS, Geller L, Risica PM, Kirtania U, Cabral HJ. Birth order and breastfeeding initiation: results of a national survey. Breastfeed Med 2008 Mar;3(1):20-27.

(205) Glanz K, Rimer BK, Lewis FM. Health Behavior and Health Education. Theory, Research and Practice. San Fransisco: Wiley & Sons; 2002.

(206) Allison P. Survival Analysis Using SAS: A Practical Guide. Cary, NC: SAS Institute INc.; 1995.

(207) Cole SR, Hernan MA. Adjusted survival curves with inverse probability weights. Comput Methods Programs Biomed 2004 Jul;75(1):45-49.

(208) Robins JM, Hernan MA, Brumback B. Marginal structural models and causal inference in epidemiology. Epidemiology 2000 Sep;11(5):550-560.

(209) Rosenbaum P.R. RDB. The central role of the propensity score in observational studies for causal effects. Biometrika 1983;70:41–55.

(210) North Carolina Breastfeeding Coalition. Ban the Bags. Available at:
http://www.ncbfc.org/index.php?option=com_content&view=category&id=40&Itemid=8
3. Accessed June 24, 2013.

(211) Osterman MJ, Martin JA, Mathews TJ, Hamilton BE. Expanded data from the new
birth certificate, 2008. Natl Vital Stat Rep 2011 Jul 27;59(7):1-28.

(212) Ford K, Labbok M. Who is breast-feeding? Implications of associated social and
biomedical variables for research on the consequences of method of infant feeding. Am J
Clin Nutr 1990 Sep;52(3):451-456.

(213) Saadeh R, Akre J. Ten steps to successful breastfeeding: a summary of the rationale
and scientific evidence. Birth 1996 Sep;23(3):154-160.

(214) United Nations Population Division. Report of the International Conference on
Population and Development. Available at:
http://www.un.org/popin/icpd/conference/offeng/poa.html. Accessed June 27, 2013.

(215) Office of the Surgeon General (US), Centers for Disease Control and Prevention
(US), Office on Women's Health (US). 2011.

(216) Labbok M, Taylor E, Parry K. Achieving Exclusive Breastfeeding in the US.
Amarillo, Texas: Hale Press; 2013.

(217) Spiegelman D, Hertzmark E. Easy SAS Calculations for Risk or Prevalence Ratios
and Differences. Am J Epidemiol 2005 1 August;162(3):199-200.

(218) Cole SR, Hernan MA. Constructing inverse probability weights for marginal
structural models. Am J Epidemiol 2008 Sep 15;168(6):656-664.

(219) Lee BK, Lessler J, Stuart EA. Weight trimming and propensity score weighting.
PLoS One 2011 Mar 31;6(3):e18174.