BREASTFEEDING INFANTS WITH CONGENITAL HEART DISEASE

by

Elsey M. Weisberg

A thesis submitted to the Faculty of the University of Delaware in partial fulfillment of the requirements for the degree of Degree of Master of Science in Human Nutrition

Spring 2018

© 2018 Elsey M. Weisberg
All Rights Reserved

BREASTFEEDING INFANTS WITH CONGENITAL HEART DISEASE

by

Elsey M. Weisberg

Approved: _____
Jillian C. Trabulsi, Ph.D., R.D.
Professor in charge of thesis on behalf of the Advisory Committee

Approved: _____
P. Michael Peterson, Ed.D.
Chair of the Department of Behavioral Health and Nutrition

Approved: _____
Kathleen S. Matt, Ph.D.
Dean of the College of Health Sciences

Approved: _____
Ann L. Ardis, Ph.D.
Senior Vice Provost for Graduate and Professional Education

ACKNOWLEDGMENTS

I would like to thank my advisor, Dr. Jillian Trabulsi, for her constant support and mentorship throughout my graduate career, in addition to the thesis process. I feel incredibly grateful to have had the opportunity to work with and learn from her, and could not have asked for a better role model. I would also like to thank my thesis committee members, Dr. Richard Fang and Rachelle Lessen, for their continued support and feedback. Finally, thank you to my family and friends for their unwavering encouragement during the past two years.

TABLE OF CONTENTS

LIST OF TABLES vi
ABSTRACT vii

Chapter

1 INTRODUCTION 1

2 REVIEW OF LITERATURE 3

2.1 Types of CHD 3

2.1.1 Cyanotic Defects 4

2.1.1.1 Hypoplastic Left Heart Syndrome 4
2.1.1.2 Tetralogy of Fallot 4
2.1.1.3 Transposition of the Great Arteries 5

2.1.2 Acyanotic Defects 5

2.1.2.1 Atrial Septal Defect 5
2.1.2.2 Ventricular Septal Defect 6
2.1.2.3 Patent Ductus Arteriosus 6

2.2 Growth of Infants with CHD 6
2.3 Feeding Infants with CHD 8
2.4 Breastfeeding Infants with CHD 8
2.5 Growth of Infants with CHD 10
2.6 Feeding Infants with CHD 11
2.7 Breastfeeding Infants with CHD 12

3 AIMS 14

4 METHODS 15

4.1 Subject Recruitment and Informed Consent 15
4.2 Study Visit Procedures 16
4.3 Anthropometrics 16
4.4 Demographic Questionnaire 17
4.5 General Interview 17

4.6 Infant Medical History 17
4.7 Monthly Infant Feeding Questionnaires 18
4.8 Feeding Definitions 18
4.9 Statistical Analysis 19

5 RESULTS 20

5.1 Parent and Infant Demographics 20
5.2 Infant Medical History 20
5.3 Anthropometry 21
5.4 Feeding Mode 21
5.5 Feeding Type 22
5.6 Feeding Patterns 23
5.7 Anthropometry Stratified by Feeding Pattern 24

6 DISCUSSION 26

7 CONCLUSION 29

REFERENCES 31

Appendix

A TABLES 36
B STUDY DOCUMENTS 41

B.1 Institutional Review Board Approval Letter 42
B.2 Informed Consent Form 43
B.3 Inclusion/Exclusion Criteria Form 49
B.4 Infant Feeding History: Visit 1 at 2 Weeks Questionnaire 50
B.5 Monthly Infant Feeding Questionnaire- In Hospital 53
B.6 Monthly Infant Feeding Questionnaire- First Home Contact 55
B.7 Monthly Infant Feeding Questionnaire- All Other Home Contacts 58
B.8 Demography Questionnaire 61
B.9 General Interview Questionnaire 64
B.10 Infant Medical History Questionnaire 66
B.11 Maternal Medications Questionnaire 67

LIST OF TABLES

Table A1- Demographic Characteristics of Infants and Parents.....36

Table A2- Infant Medical History at Two Weeks 38

Table A3- Feeding Type and Mode for the First Four Months, by Month.....38

Table A4 – Anthropometry for the First Four Months, by Month.....39

Table A5 – Breastfeeding Patterns for the First Four Months.....39

Table A6- Anthropometry Stratified by Feeding Pattern for the First Four Months of Life, by Month 40

ABSTRACT

Congenital heart disease (CHD) is the most common birth defect in the United States. Infants with CHD are known to have a high incidence of feeding challenges which compromise nutritional intake and contribute to compromised growth. Historically, it was recommended that infants with CHD be bottle fed, because breastfeeding was considered too physiologically laborious. Research demonstrated otherwise, and this, paired with the known nutritional benefits of breastfeeding has led to the recommendation that infants with CHD be breastfed/receive breast milk (BM). There is lack of data on the course of breastfeeding/feeding BM in this population in the first year of life and its effects, if any, on growth outcomes. The data presented herein are part of an on-going, observational study of breastfeeding in infants with CHD. A total of 46 infants have been enrolled and completed visits through 4 months of age. With respect to exclusivity and duration of breastfeeding/feeding BM, at two weeks of age, the majority of infants were fed BM exclusively (N=29, 63%), 11 infants (23.9%) were fed a mix of BM and formula, and six infants (13.0%) were fed formula exclusively. By four months of age, the number of infants receiving exclusively BM decreased to 14 (31.1%), six infants (13.3%) were fed BM fortified with powder formula, 16 infants (35.6%) received a mix of BM and formula, and nine infants (20.0%) were fed formula only. With respect to the within subject breastfeeding/feeding BM pattern over time, we identified three feeding patterns:

“principally BM” for infants who received BM as the only source of nutrition for first four months of life, “BM/Mix” for infants that received breast milk from birth up to 1 month of age, then changed to a mix of breast milk and formula for the next three months”, and “BM/Mix/Formula” to define infants who received breast milk at birth, then a mix of breast milk and formula, and then exclusive formula feeding for the next three months of life. We next examined the influence of these feeding pattern on trajectories of Z-scores over the first four months of life. We found no significant group × time interactions in weight for age Z-scores (WAZ; p=0.385), length for age Z-scores (LAZ; p=0.755), or height for age Z-scores (HCZ; p=0.918), indicating these growth trajectories did not differ over time by feeding group/pattern. There was however a significant group × time interaction for WLZ (p=0.035); infants in the principally BM feeding pattern tended to be leaner at four months compared to those in the BM/Mix and BM/Mix/Formula categories. The data presented in this thesis are from an interim analysis, all data analyses will be repeated when the study is complete (n=75 infants).

Chapter 1

INTRODUCTION

Congenital heart disease (CHD) is defined as a cluster of diseases characterized by structural heart issues that occur during fetal development and are often diagnosed in utero.[1] CHD is the most common birth defect in the United States, affecting 1% of live births or 40,000 infants each year.[1,2] Both genetic and environmental factors are thought to play a role in CHD.

The mortality rate for infants with CHD in 2006 was 37.7%, making CHD the leading cause of infant mortality in the United States.[3,4] Fortunately, survival rates for infants with CHD have improved, with the mortality rate declining 17.3% between 1999 and 2006.[3] Race and ethnicity differences exist, with higher mortality rates seen in the non-Hispanic black population as compared with non-Hispanic white population of infants with CHD.[3] Respiratory distress is common in infants with CHD, which can lead to both feeding and growth issues during infancy.[2] The majority of infants, when treated with medical therapies or surgical intervention, can live a productive adult life.[1]

Feeding issues are common to infants with CHD, and mothers have reported difficulties such as choking, swallowing, and suckling among others.[5] As a result, nutritional intake is often decreased, leading to short and long-term growth challenges

in this population.[6,7] Poor growth, an indirect indicator of malnutrition, has been found to be related to increased length of hospital stay and increased incidence of mortality.[8] Long term malnutrition is of concern as it can affect neurodevelopmental outcomes.[9] Breastfeeding is the current recommendation of feeding for all infants, but further evidence is necessary to determine the relationship between breastfeeding and growth in infants with CHD.

Chapter 2

REVIEW OF LITERATURE

2.1 Types of CHD

Congenital heart defects disrupt the normal circulatory pattern of the heart. In a healthy heart, deoxygenated blood from the body enters the right side of the heart through the vena cava veins. The blood then moves through the right atrium and through the tricuspid valve to the right ventricle. Next it flows through the pulmonary valve to the pulmonary artery, and on to the lungs. Once oxygenated in the lungs, the newly oxygenated blood passes from the lungs to the left side of the heart, where the blood travels through the pulmonary vein into the left atrium, through the mitral valve, then to the left ventricle. From the left ventricle blood then goes through the aortic valve, to the aorta, and finally back to the body where it delivers the oxygenated blood.[10]

In a heart with a congenital defect, this circulatory pattern is interrupted at one or more points in this pathway. There are at least 18 different recognized congenital heart defects, as well as variations of these defects, which range in severity and surgical requirements.[11] Each defect can be classified as either cyanotic or acyanotic.[1] Cyanotic heart defects are characterized by the bluish discoloration of an infant's skin, indicating a low blood oxygen concentration.[1] Cyanotic and acyanotic congenital

heart defect classifications also differ in that infants with cyanotic heart defect have been found to have significant delays in feeding readiness as compared to infants with acyanotic heart defects.[5,11] Common cyanotic heart defects include hypoplastic left heart syndrome, tetralogy of fallot, and transposition of the great arteries. Common acyanotic heart defects include atrial septal defect, ventricular septal defect, and patent ductus arteriosus.

2.1.1 Cyanotic Defects

2.1.1.1 Hypoplastic Left Heart Syndrome

Hypoplastic left heart syndrome (HLHS) is a defect where the left-heart structures are underdeveloped; HLHS often includes the left ventricle, aortic valve, and mitral valve.[2,11] The underdeveloped left heart causes a disruption in pattern of blood flow of oxygenated blood returning to the heart from the lungs, or from the left ventricle to the aorta.[2] Immediate surgical intervention or a heart transplant is necessary for infants with HLHS.[11]

2.1.1.2 Tetralogy of Fallot

Tetralogy of fallot (TOF) is a defect consisting of four structural abnormalities that result in limited blood flow to the lungs of varying degrees. These four abnormalities include ventricular septal defect (a hole between the left and right ventricles), pulmonary stenosis (a heart valve that may not open, which causes blood to flow out of the heart and into the lungs) right ventricular hypertrophy (thickened

walls of the right ventricle), and a hypertrophic aortic valve that leads to both right and left ventricles, unlike only the left ventricle such as in a healthy heart.[1] For this reason, infants with TOF were historically called "blue babies". TOF requires surgical intervention very early after delivery.[2]

2.1.1.3 Transposition of the Great Arteries

Transposition of the great arteries (TGA) is a defect in which the right ventricle and the aorta are in switched places from a normal heart, causing blood to flow in two different and separate circulation loops.[11] With TGA, oxygenated blood from the lungs is continuously pumped through the left atrium to the left ventricle, and then back to the lungs; oxygenated blood is never pumped out to the body. As such the infant's blood quickly becomes under-oxygenated. TGA requires immediate surgical intervention.[2]

2.1.2 Acyanotic Defects

2.1.2.1 Atrial Septal Defect

Atrial septal defect (ASD) occurs when there is a hole in the heart between the atria, also known as the interatrial septum. This hole leads to a blood volume overload on the right side of the heart. ASD if very small can be treated medically, or if moderate to large, is treated with surgical repair.[11]

2.1.2.2 Ventricular Septal Defect

Ventricular septal defect (VSD) consists of a hole in the heart between the lower right and lower left ventricles, also known as the interventricular septum.[11] Oxygenated and deoxygenated blood are able to mix, which leads to a blood volume overload on the left side of the heart. Depending on the size of the hole, medication or surgical repair may be necessary for infants with VSD.[2]

2.1.2.3 Patent Ductus Arteriosus

Patent ductus arteriosus is the sixth most common congenital heart defect. This defect occurs when the duct between the pulmonary artery and the aorta (the ductus arteriosus) does not close properly after birth.[2] Oxygenated and deoxygenated blood are able to mix, which increases the volume of blood the heart and lungs need to pump.[2] In some cases the duct closes on its own, but surgical intervention may be necessary.[11]

2.2 Growth of Infants with CHD

Infants with CHD often have difficulty with growth.[12-14] Issues with weight start early. The incidence of very low birth weight (VLBW) is 18% in infants with CHD as compared to 8% in the general population.[15] Weight gain and growth issues continue throughout the first year of life. A study of 89 infants, 1-45 months of age with cyanotic and acyanotic CHD found 58 of the 89 subjects (56%) were below the fifth percentile for weight.[16] Another study of children with CHD ranging in age from

1 day to 4 years old reported that nearly 52% had a weight below the growth chart 3rd percentile and 37% had a length/height below the 3rd percentile.[17] In a more recent study of three-month old infants with CHD, postoperative weight for age (WAZ) and length for age (LAZ) Z-scores were -1.1 ± 1.1 and -0.7±1.1 indicating that as a group these infants weighed less and were shorter than their healthy counterparts.[12] And another study of infants less than one year of age with congenital heart defects also found mean WAZ scores ranging from -1.15 to -0.24, and mean LAZ scores ranging from -1.17 to -0.12.[18]

The type of heart defect may impact growth as well; infants with a cyanotic heart defect with pulmonary hypertension have been shown to be more prone to malnutrition and growth failure than infants with other congenital heart defects.[16] Importantly, poor growth is related to outcomes, a matched control study of 31 infants with CHD who survived versus died following surgical intervention found that 17 of 31 children who died had a weight for age Z-score below -2.0 at the time of last recorded weight, as compared with 4 of 31 children who survived.[19] Finally, the impact on growth may be long lasting, while weight status appears to improve to a greater degree than height status[20,21], 8 year old children with CHD have been shown to have body mass index z-score (BMIZ) and height for age (HAZ) lower than the general population (mean BMIZ: -0.6 ± 1.5, mean HAZ: -0.8 ±1.3).[21]

2.3 Feeding Infants with CHD

Feeding challenges are common in infants with CHD.[7] Feeding challenges for infants with CHD include vomiting and difficulty swallowing, sucking, very long feedings, lack of hunger, and difficulty breathing during feeding.[5,7,22,23] These challenges can easily lead to under-nutrition, which if chronic can lead to significantly stunted growth in infants with CHD.[16,19,23] Breast milk is the preferred source of nutrition for all infants, including infants with CHD.[24] If receiving breast milk, infants may feed directly at the breast, or via the bottle. Some infants are unable to consume enough milk orally and may require supplemental tube feeding. If a mother is unable to produce sufficient breast milk volume or does not breastfeed their infant, infant formula is the next best feeding alternative. Infant formula may be added as a powder to breast milk to increase the energy and nutrient content of breast milk. Or reconstituted infant formula may be combined with breast milk to increase the volume of milk available for the infant.

2.4 Breastfeeding Infants with CHD

Historically, infants with CHD were thought unable to breastfeed, because it was hypothesized that nursing required too much effort from the infant and would wear them out. As such mothers of infants with CHD were encouraged to bottle feed rather than breastfeed in the hospital setting.[16,23] However, there is evidence that suggests breastfeeding is not a physiologically laborious as once thought.[16,25] A cross-over study by Marino et al (1995) measured oxygen saturations using pulse oximetry

in seven infants with CHD while bottle feeding and again while breastfeeding. This study found a significant drop in oxygen saturation during bottle feedings as compared with breast feedings, meaning less cardiorespiratory stress for infants with CHD during breastfeeding than bottle feeding.[25]

Breastfeeding has been successfully initiated post-surgery, but infants with CHD still have a lower prevalence of breastfeeding than the healthy infant population.[7] Recent research focuses on the positive effects of encouraging mothers of infants with CHD to breastfeed. Studies suggests that with proper in-hospital lactation support, the majority of mothers are able to initiate breastfeeding with infants with CHD.[6,26] Lactation and education support in the hospital have a positive impact on ability to initiate breastfeeding for these mothers.[27,28]

Research on growth of infants with CHD as it relates to feeding practices is very limited. A study comparing breast and bottle feeding in infants with CHD found that infants who did not receive any amount of breast milk fell significantly farther off their growth curves than the infants who received breast milk as part of their diet.[6] A more recent study found that the type of feeding, specifically breast milk or formula, did not significantly impact growth in the first few days following surgical intervention.[15] There is minimal research on how breastfeeding exclusivity and duration relate to growth in the first year of the life in infants with CHD.

2.5 Growth of Infants with CHD

Infants with CHD often have difficulty with growth.[12-14] Issues with weight start early. The incidence of very low birth weight (VLBW) is 18% in infants with CHD as compared to 8% in the general population.[15] Weight gain and growth issues continue throughout the first year of life. A study of 89 infants, 1-45 months of age with cyanotic and acyanotic CHD found 58 of the 89 subjects (56%) were below the fifth percentile for weight.[16] Another study of children with CHD ranging in age from 1 day to 4 years old reported that nearly 52% had a weight below the growth chart 3rd percentile and 37% had a length/height below the 3rd percentile.[17] In a more recent study of three-month old infants with CHD, postoperative weight for age (WAZ) and length for age (LAZ) Z-scores were -1.1 ± 1.1 and -0.7±1.1 indicating that as a group these infants weighed less and were shorter than their healthy counterparts.[12] And another study of infants less than one year of age with congenital heart defects also found mean WAZ scores ranging from -1.15 to -0.24, and mean LAZ scores ranging from -1.17 to -0.12.[18]

The type of heart defect may impact growth as well; infants with a cyanotic heart defect with pulmonary hypertension have been shown to be more prone to malnutrition and growth failure than infants with other congenital heart defects.[16] Importantly, poor growth is related to outcomes, a matched control study of 31 infants with CHD who survived versus died following surgical intervention found that 17 of 31 children who died had a weight for age Z-score below -2.0 at the time of last recorded weight, as compared with 4 of 31 children who survived.[19] Finally, the

impact on growth may be long lasting, while weight status appears to improve to a greater degree than height status[20,21], 8 year old children with CHD have been shown to have body mass index z-score (BMIZ) and height for age (HAZ) lower than the general population (mean BMIZ: -0.6 ± 1.5, mean HAZ: -0.8 ±1.3).[21]

2.6 Feeding Infants with CHD

Feeding challenges are common in infants with CHD.[7] Feeding challenges for infants with CHD include vomiting and difficulty swallowing, sucking, very long feedings, lack of hunger, and difficulty breathing during feeding.[5,7,22,23] These challenges can easily lead to under-nutrition, which if chronic can lead to significantly stunted growth in infants with CHD.[16,19,23] Breast milk is the preferred source of nutrition for all infants, including infants with CHD.[24] If receiving breast milk, infants may feed directly at the breast, or via the bottle. Some infants are unable to consume enough milk orally and may require supplemental tube feeding. If a mother is unable to produce sufficient breast milk volume or does not breastfeed their infant, infant formula is the next best feeding alternative. Infant formula may be added as a powder to breast milk to increase the energy and nutrient content of breast milk. Or reconstituted infant formula may be combined with breast milk to increase the volume of milk available for the infant.

2.7 Breastfeeding Infants with CHD

Historically, infants with CHD were thought unable to breastfeed, because it was hypothesized that nursing required too much effort from the infant and would wear them out. As such mothers of infants with CHD were encouraged to bottle feed rather than breastfeed in the hospital setting.[16,23] However, there is evidence that suggests breastfeeding is not a physiologically laborious as once thought.[16,25] A cross-over study by Marino et al (1995) measured oxygen saturations using pulse oximetry in seven infants with CHD while bottle feeding and again while breastfeeding. This study found a significant drop in oxygen saturation during bottle feedings as compared with breast feedings, meaning less cardiorespiratory stress for infants with CHD during breastfeeding than bottle feeding.[25]

Breastfeeding has been successfully initiated post-surgery, but infants with CHD still have a lower prevalence of breastfeeding than the healthy infant population.[7] Recent research focuses on the positive effects of encouraging mothers of infants with CHD to breastfeed. Studies suggests that with proper in-hospital lactation support, the majority of mothers are able to initiate breastfeeding with infants with CHD.[6,26] Lactation and education support in the hospital have a positive impact on ability to initiate breastfeeding for these mothers.[27,28]

Research on growth of infants with CHD as it relates to feeding practices is very limited. A study comparing breast and bottle feeding in infants with CHD found that infants who did not receive any amount of breast milk fell significantly farther off their growth curves than the infants who received breast milk as part of their diet.[6] A

more recent study found that the type of feeding, specifically breast milk or formula, did not significantly impact growth in the first few days following surgical intervention.[15] There is minimal research on how breastfeeding exclusivity and duration relate to growth in the first year of the life in infants with CHD.

Chapter 3

AIMS

The overarching goal of this study is to utilize data from a prospective, observational study to examine breastfeeding/feeding breast milk practices in the first four months of life in infants with congenital heart defects (CHD) and determine the relationship between breastfeeding/feeding breast milk and growth.

Specific Aim 1: Describe breastfeeding/feeding breast milk practice in infants with congenital heart defects (CHD) in the first year of life. Because mothers of infants with CHD are provided encouragement and support to breastfeed,[28] we hypothesize that incidence of infants with CHD receiving any breast milk will be comparable to the general population.

Specific Aim 2: Describe growth patterns of infants with CHD and determine the relationship between growth patterns and breastfeeding/feeding breast milk practices in the first year of life. Since infants with CHD who receive breast milk have been found to have better growth outcomes,[6] we hypothesize that infants with greater duration of receiving any breast milk, will have more normative growth measures as compared to those with a shorter duration of receiving any breast milk.

Chapter 4

METHODS

4.1 Subject Recruitment and Informed Consent

The study protocol, data collection questionnaires, recruitment materials, and informed consent form were reviewed and approved by the Institutional Review Board (IRB) at the Children's Hospital of Philadelphia and the IRB at the University of Delaware prior to study initiation. The study is currently underway and the goal is to enroll 75 mother-infant dyads.

Subjects are recruited from the cardiac intensive care unit (CICU) at Children's Hospital of Philadelphia (CHOP). Inclusion criteria for participants requires that: at birth, infants are term (>37 and <42 weeks gestation at birth), singleton, and appropriate for gestational age; and at the time of enrollment, infants have CHD diagnosis that requires surgical intervention prior to discharge, are between 0 to 21 days of age, and have a mother >18 years of age, English speaking, and planning to breastfeed. Infants were excluded from the study if they had any other physical, neurological, or physiologic anomalies known to affect feeding (e.g. cleft palate, inborn errors of metabolism).

Subjects who meet the inclusion criteria are approached in the CICU by the study Principal Investigator and informed about the study. If the mother chooses to

participate in the study, the informed consent procedure is completed for the mother-infant dyad.

4.2 Study Visit Procedures

Once a mother-infant dyad is enrolled (informed consent completed), the subject is assigned a unique identification number. The study consists of nine points of contact with the subject spread throughout the first year of life. The first contact (visit) occurs in the first two weeks of life when the infant is still hospitalized. Thereafter study contacts (visits or telephone calls) occur at 1, 2, 3, 4, 6, 8, and 10 months of age.

The first visit occurs in the CICU and consists of the following forms: demographic questionnaire, general interview questionnaire, infant feeding history questionnaire, and infant medical history questionnaire. Visit two occurs either in hospital or at home depending on the infant, and consists of an infant feeding questionnaire and a maternal medication questionnaire. Visits three through nine occur via telephone while the subject is home, and consist of an infant feeding questionnaire and a maternal medication questionnaire. See the Appendix for all questionnaires. Anthropometric measures are also collected for all study contacts.

4.3 Anthropometrics

Anthropometric measurements include infant weight, length and head circumference. If an infant is inpatient (hospitalized) or receives care at an outpatient

CHOP care facility, weight and length are recorded from electronic health record. If at any visit the infant is not receiving care at a CHOP facility, the infant's weight, length, and head circumference are obtained from their primary care provider's electronic health record.

4.4 Demographic Questionnaire

The demographic questionnaire is completed at the first study visit. This questionnaire collects information related to maternal and paternal age, race, ethnicity, education, occupation, and participation in government programs.

4.5 General Interview

The general interview form is completed at the first study visit. This form asks questions regarding maternal and paternal age, marital status, height and weight, as well as infant age, gender, age and gender of the infant's siblings. This form also obtains additional data on those living in the household with the infant.

4.6 Infant Medical History

Infant medical history is completed at the first study visit. This form asks questions pertaining to the infant's CHD diagnosis, gestational age, weight, length, surgical history and any additional diagnoses.

4.7 Monthly Infant Feeding Questionnaires

Monthly Infant Feeding Questionnaires (MIFQ) are completed at each study visit. This questionnaire asks questions pertaining to feeding practices, breast milk, and breastfeeding, pumping breast milk, and enteral tube feeding.

4.8 Feeding Definitions

The term breastfeeding refers to infants who are feeding breast milk exclusively by nursing. The term breast milk refers to infants who are receiving breast milk, regardless of feeding mode (nursing or via bottle). With respect to feeding patterns over the first four months of life, we used the term 'principally breast milk (BM)' for infants who received breast milk as the main source of nutrition, with only a day or two of infant formula use in the first four months of life (e.g., a mother reported her infant was exclusively receiving breast milk except for 1 day when infant was hospitalized and received infant formula). The term 'BM/Mix' was used to define infants that received breast milk from birth up to 1 month of age, then feedings changed to a mix of breast milk and formula for the next three months of life. The term 'BM/Mix/Formula' was used to define infants who received breast milk at birth, then a mix of breast milk and formula, and then switched to exclusive formula feeding during the next three months of life.

4.9 Statistical Analysis

The data from this prospective, observational study was entered into REDCap, a secure web-based electronic data capture and management system. Continuous variables were summarized using number of observations, mean, standard deviation, median, minimum and maximum. Categorical variables were be summarized using frequency and percentages of subjects. To assess aim 1, examination of breastfeeding/feeding breast milk practice in infants with CHD in the first four months of life, descriptive statistics (number, percentage) were utilized to describe proportion of infants fed 'breast milk only' and 'any breast milk', 'breast milk fortified with formula', mix of breast milk and formula, 'formula only' at monthly intervals in the four months of life. To assess aim 2, the relationship between growth patterns and breastfeeding/feeding breast milk practices in the first four months of life, descriptive statistics (means, SD) were used to describe growth parameters (weight for age [WAZ], length for age [LAZ], weight for length [WLZ], body mass index [BMIZ]). A generalized estimating equation (GEE) was used to determine if the growth trajectories (weight for age Z-scores, length for age Z-scores, weight for length Z-scores, head circumference Z-scores) of infants with CHD who receive 'breast milk only', 'any breast milk', 'breast milk fortified with formula', mix of breast milk and formula, and 'formula only' differed in the first four months of life.

Chapter 5

RESULTS

5.1 Parent and Infant Demographics

Parent and infant demographics for the 46 mother-infant dyads are summarized in **Table A1**. Thirty-three infants (71.7%) are male and 42 subjects (91.3%) are non-Hispanic or Latino. Thirty-seven infants (80.4%) are white or Caucasian, six infants (13.0%) are black or African American with the remaining infants two or more races (4.3%) or 'other' (2.2%).

The majority of mothers (n=25, 54.3%) report completing 1-4 years of college, and 15 mothers (32.6%) completed a graduate education. Similarly, the majority of fathers reported completing 1-4 years of college (n=25, 54.3%), and nine fathers (19.6%) completed more than four years of college as their highest degree. The mean age for mothers and fathers is 31.0.0±5.0 and 32.9±5.9, respectively.

5.2 Infant Medical History

Infant medical history is summarized in **Table A2.** At two weeks of age, the majority of infants have a CHD diagnosis of hypoplastic left heart syndrome (HLHS; n=20, 43.5%). Five infants have a diagnosis with truncus arteriosus (TA; 10.9%), and

four infants are diagnosed with dextro-Transposition of the great arteries (TGA-D; 8.7%).

5.3 Anthropometry

Anthropometric data for the first four months of life for infants are summarized in **Table A4**. At birth, the mean weight for age Z-score (WAZ) was 0.1±1.0, the mean length for age Z-score (LAZ) was 0.04±1.2, and the mean weight for length Z-score (WLZ) was 0.1±1.4; head circumference Z-scores (HCZ) were not reported at birth. At two weeks of age, the mean WAZ was -0.5±1.5, mean LAZ was -0.8±1.2, mean HCZ was -1.1±1.2, and the mean WLZ was -0.1±1.7. By one month of age, the mean WAZ, LAZ, HCZ, AND WLZ were -1.0±1.1, -1.0±1.1, -1.1±0.9 and -0.3±1.4, respectively. At two months of age, mean WAZ, LAZ, HCZ, AND WLZ were -1.1±1.1, -1.3±1.2, -1.1±1.2 and 0.1±1.2, respectively. At four months of age, the mean WAZ was -1.2±1.0, mean LAZ was -1.1±1.0, the mean HCZ was -1.6±4.1, and the mean WLZ was -0.6±1.3.

5.4 Feeding Mode

With respect to how the infants were fed (feeding mode), at two weeks of age (study enrollment), the majority of infants (N=32, 70%), were fed via a mix of breastfeeding, bottle feeding and a nasogastric (NG) tube feed with no infants exclusively breast fed. At one month of age, 12 infants (26.1%) were fed via a mix of

breast and bottle feeding, 11 infants (24.0%) were fed via a bottle exclusively, 10 infants (21.7%) were fed via mix of a bottle and nasogastric (NG) tube feeding, seven infants (15.2%) were fed via a mix of breastfeeding, bottle feeding and a nasogastric tube, while five infants (10.9%) were exclusive fed via a NG tube feeding. Only one infant (2.2%) was exclusively breastfed at one month of life. At two months of life, 17 infants (37.0%) were fed through a mix of breast and bottle feeding, and 17 infants (37.0%) were fed exclusively via a bottle, 4 infants (8.7%) were fed by a mix of bottle and NG tube, and 4 infants (8.7%) were exclusively fed via NG. At three months of life, the majority of infants were exclusively bottle-fed (N=18, 39.1%), 12 infants (26.1%) were fed through a mix of breast and bottle feeding, four infants (8.7%) were exclusively breastfed at three months of life. At four months of life, the majority of infants were still fed exclusively through a bottle (N=21, 45.7%), eight infants (17.4%) were fed though a mix of breast and bottle feeding, six infants (13.0%) were fed through both a bottle and a NG tube, four infants (8.7%) were exclusively breasted at four months of life.

5.5 Feeding Type

To assess specific aim 1, describing breastfeeding/feeding breast milk practices of infants with CHD in the first four months of life, the proportion of infants fed 'breast milk only', 'any breast milk', 'breast milk fortified with formula', mix of breast milk and formula, 'formula only' was summarized for each visit (**Table A3)**. At two weeks of age, the majority of infants were fed breast milk exclusively (N=29,

63%). Eleven infants (23.9%) were fed a mix of breast milk and formula, and six infants (13.0%) were fed formula exclusively. At one month of age, the number of infants receiving exclusively breast milk dropped to 16 infants (34.8%), 18 infants (39.1%) were fed breast milk fortified with powder formula, nine infants (19.6%) were fed a mix of breast milk and formula, and three infants (6.5%) received formula exclusively. At two months of age the number of infants receiving exclusively breast milk remained steady at 15 infants (32.6%), eight infants (17.4%) were fed breast milk fortified with powder formula, eight infants (17.4%) were fed a mix of breast milk and formula, and 15 infants (32.6%) were fed formula only. At three months of life, the number of infants receiving exclusively breast milk remained at 15 infants (33.3%), and only four infants (8.9%) were fed breast milk fortified with powder formula, 12 infants (26.7%) were fed a mix of breast milk and formula, and 14 infants (31.3%) were fed formula only. Finally, at four months of life, the number of infants receiving exclusively breast milk continued to be about the same at 14 infants (31.1%), and six infants (13.3%) were fed breast milk fortified with powder formula, 16 infants (35.6%) received a mix of breast milk and formula, and nine infants (20.0%) were fed formula only.

5.6 Feeding Patterns

Feeding patterns for the first four months of life are summarized in **Table A5.** Infants who received breast milk as the main food source for the first four months of

life were categorized as “Principally BM”. Infants who received breast milk from two weeks of age up to one month, then received a mix of breast milk and formula for the first four months of life were categorized as “BM, Mix”. Infants who received breast milk at two weeks, then a mix of breast milk and formula, and then switched to exclusive formula during the first four months of life were categorized as “BM, Mix, Formula”. During the first four months of life, fourteen infants (30.4%) received breast milk as the main source of nutrition. Eighteen infants (39.1%) received breast milk from two weeks up to 1 month of age, then received a mix of breast milk and formula for the remainder of the first four months of life. Fourteen infants (30.4%) received breast milk at two weeks of age, followed by a mix of breast milk and formula, and then exclusive formula feeding during the first four months of life.

5.7 Anthropometry Stratified by Feeding Pattern

Anthropometry data stratified by feeding pattern are summarized in **Table A6**. For infants who received principally BM in the first four months of life, at two weeks of age, mean WAZ was -0.2±2.0, mean LAZ was -0.5±1.0, mean HCZ was -0.8±1.4 and mean WLZ was 0.5±2.4. At four months of life, WAZ, LAZ, HCZ and WLZ were -0.9±1.0, -1.1±0.9, -0.6±1.3 and -0.9±1.3, respectively. For infants categorized as “BM, Mix”, two weeks of age, mean WAZ was 0.7±1.2, mean LAZ was -0.7±1.3, mean HCZ was -1.3±1.3 and mean WLZ was -0.7±1.0. At four months of life, WAZ, LAZ, HCZ and WLZ were -1.3±1.2, -1.0±1.1, -0.7±1.1 and -0.3±1.3, respectively. For

infants categorized as “BM, Mix, Formula”, at two weeks of age, mean WAZ was -0.9±1.1, mean LAZ was -1.3±1.3, mean HCZ was -1.0±1.0 and mean WLZ was --0.1±1.0. At four months of life, WAZ, LAZ, HCZ and WLZ were -1.2±0.8, -1.2±1.1, -0.8±1.1 and -0.1±1.1, respectively. Across all feeding patterns, WAZ and LAZ showed a decreasing trend.

To determine if growth trajectories differed over type by feeding pattern (aim 2), generalized estimating equations (GEEs) that included feeding group (principally BM, BM/Mix, BM/Mix/Formula), time, and group × time interaction were conducted on anthropometric outcomes. The GEE approach accounts for the repeated measurements of outcomes over time for each infant and examines whether the slopes of the line created differ by groups. Visualization of the correlation structure for inclusion within the GEE model was conducted and for all anthropometric Z-scores, an autoregressive correlation structure was identified. For growth Z-scores measured in the first four months of life, we found no significant group × time interactions in WAZ (p=0.385), LAZ (p=0.755), or HCZ (p=0.918) indicating these growth trajectories did not differ over time by feeding group/pattern. There was a significant group × time interaction for WLZ (p=0.035); infants in the principally BM feeding pattern tended to be leaner at four months compared to those in the BM/Mix and BM/Mix/Formula categories. These data are preliminary and will be repeated when the data set is complete with 75 infants.

Chapter 6

DISCUSSION

The overall aim of this study was to determine the relationship between feeding breast milk/breastfeeding and growth in infants with CHD during the first four months of life. It is important to note that the infants in this study had complex heart defects (e.g., hypoplastic left heart syndrome, truncus arteriosis, transposition of the great arteries), that require multiple surgical interventions in the first year of life. The data presented in this thesis are preliminary (n=46 infants) and all analyses will be repeated when study is complete (n=75 infants). We had two main findings, the first is related to the proportion of infants that receive any breast milk in the first four months of life. We compared the results of our study, to data from the Infant Feeding Practices II (IFPII) study, a longitudinal study of infant feeding practices from birth (n=2907) through 12 months of age (n=1782 infants)[29.] In our study of infants with CHD, 93.5% of infants were receiving any breast milk at 1 months of age, while in the IFPII study, only 74% of infants were receiving any BM.[29] At two months of age, 67.4% of infants with CHD were receiving any breast milk, which was comparable to the IFPII study which reported 65.4% of infants receiving any BM.[29] The proportions were comparable at three months as well. By four months of age, approximately 80% of infants with CHD were receiving any BM, which was a higher percentage than the

57.2% found in the IFPII study.[29] These suggest that the proportion of infants who receive any breast milk is comparable or greater than the general population.

The secondary aim of this study was to determine if the feeding pattern of infant (i.e., primarily BM, BM followed by a mix of BM and formula, or BM, followed by a mix of BM and formula, and then exclusively formula) impacted growth outcome measures. First, for feeding patterns, Z-scores decreased over time. This finding is consistent with data from another study which found that at birth, infants with CHD had an average WAZ=0.28, which dropped to -0.20 by three months of age.[31] Another study found that Z-scores were lower in infants with CHD who underwent surgery after ten days of life when compared to infants who underwent heart surgery during the first days of life, but that Z-scores of both groups were similar by six months.[18] Our study did not analyze Z-scores in relation to surgery date, however this finding should be further explored with the full data set including six-month time points.

To our knowledge, this is the first study to evaluate growth of CHD infants over time based on feeding patterns. We found no significant differences in WAZ, LAZ, or HCZ based on the feeding pattern in the first four months of life. We did find that infants who were primarily BM fed had a lower WLZ at four months of age compared to the other feeding patterns. Interestingly, this finding is consistent with data from other studies of healthy infants which found that BM-fed infants have a lower WLZ in the first year of life.[32-35] Whether our finding at four months of age remains when all infants are enrolled (n=75 infants), and whether the observed WLZ

differences continue through 12 months of age will be determined when this 12-month observational study is complete.

A strength of this study is its longitudinal design, which allows for examination of both feeding type, feeding pattern, and growth trajectories over time. The preliminary nature of this data is a weakness. This interim analysis included data for only the first four months of life in 46 of the 75 infants. The analyses used in this study will be repeated once all subjects have completed the 12-month study.

Chapter 7

CONCLUSION

Infants with congenital heart disease are known to have feeding difficulties (e.g., chocking and difficulty swallowing)[5] and poor growth.[12-14, 16, 17] These feeding difficulties may contribute to the poor growth outcomes seen in this population.[6,7] It has been suggested the type of feeding (breast milk or infant formula), may play a role in growth. Breastfeeding is recommended for all infants, whether healthy or with chronic disease. While it was previously thought that breastfeeding was more laborious for infants with congenial heart disease, and this hypothesis was proven untrue[25], there are no longitudinal studies on the effect of the type of feeding on growth in infants with CHD.

The present study describes breastfeeding practices of infants with CHD through four months of age, and also compares infant feeding patterns to growth outcomes. This interim analysis found that what an infant is fed (principally breast milk, breast milk followed by a mix of breast milk and formula, or breast milk then a mix, and then exclusive formula) did not affect WAZ and LAZ growth trajectories over the course of four months. Our interim analyses did show that WLZ was significantly lower at four months of life for the infants who were principally fed BM when compared to other feeding patterns, but it is important to note that this same

finding has been reported in healthy infants as well. That WAZ and LAZ did not differ by feeding patterns shows that weight gain and length gain trajectories were similar among the groups. The results of this interim analysis are preliminary and should be further explored when the study is complete. Results of this study have the potential to impact future feeding guidance for mothers of infants with CHD with an overall goal of achieving normative growth patterns in this population.

REFERENCES

1. Common types of heart defects. http://www.heart.org/HEARTORG/Conditions/CongenitalHeartDefects/AboutCongenitalHeartDefects/Common-Types-of-Heart Defects_UCM_307017_Article.jsp#.WYJ9AzvuaI0).

2. Congenital heart defects. http://www.childrenshospital.org/conditions-and-treatments/conditions/congenital-heart-defects/overview. Accessed June 30, 2017.

3. Gilboa SM, Salemi JL, Nembhard WN, Fixler DE, Correa A. Mortality resulting from congenital heart disease among children and adults in the united states, 1999 to 2006. *Circulation*. 2010;122(22):2254-2263.

4. Hoffman JIE, Kaplan S. The incidence of congenital heart disease. *Journal of the American College of Cardiology*. 2002;39(12):1890-1900.

5. S R Jadcherla, A S Vijayapal, S Leuthner. Feeding abilities in neonates with congenital heart disease: A retrospective study. *Journal of Perinatology*. 2009;29(2):112-118. http://dx.doi.org/10.1038/jp.2008.136. doi: 10.1038/jp.2008.136.

6. Combs VL, Marino BL. A comparison of growth patterns in breast and bottle-fed infants with congenital heart disease. *Pediatric nursing*. 1993;19(2):175.

7. Medoff-Cooper B, Naim M, Torowicz D, Mott A. Feeding, growth, and nutrition in children with congenitally malformed hearts. *Cardiol Young*. 2010;20 Suppl 3:149-153.

8. Eskedal LT, Hagemo PS, Seem E, et al. Impaired weight gain predicts risk of late death after surgery for congenital heart defects. *Arch Dis Child*. 2008;93(6):495-501.

9. Fuller S, Nord AS, Gerdes M, et al. Predictors of impaired neurodevelopmental outcomes at one year of age after infant cardiac surgery. *Eur J Cardiothorac Surg*. 2009;36(1):40-47.

10. How the heart works. https://www.nhlbi.nih.gov/health/health-topics/topics/chd/heartworks.

11. Overview of congenital cardiovascular anomalies. http://www.merckmanuals.com/professional/pediatrics/congenital-cardiovascular-anomalies/overview-of-congenital-cardiovascular-anomalies?qt=congenitlheartdisease&alt=sh.http://www.merckmanuals.com/professional/pediatrics/congenital_cardiovascular_anomalies/overview_of_congenital_cardiovascular_anomalies.html?qt=congenitlheartdisease&alt=sh). Accessed June 30, 2017.

12. Irving SY, Medoff-Cooper B, Stouffer NO, et al. Resting energy expenditure at 3 months of age following neonatal surgery for congenital heart disease. *Congenit Heart Dis*. 2013;8(4):343-351.

13. Dooley KJ, Bishop L. Medical management of the cardiac infant and child after surgical discharge. *Crit Care Nurs Q*. 2002;25(3):98-104.

14. Forchielli ML, McColl R, Walker WA, Lo C. Children with congenital heart disease: A nutrition challenge. *Nutr Rev*. 1994;52(10):348-353.

15. Rosti L, Vivaldo T, Butera G, Chessa M, Carlucci C, Giamberti A. Postoperative nutrition of neonates undergoing heart surgery. *Pediatr Med Chir*. 2011;33(5-6):236-240.

16. Varan B, Tokel K, Yilmaz G. Malnutrition and growth failure in cyanotic and acyanotic congenital heart disease with and without pulmonary hypertension. *Archives of disease in childhood*. 1999;81(1):49-52.

17. Mitchell IM, Logan RW, Pollock JC, Jamieson MP. Nutritional status of children with congenital heart disease. *Br Heart J*. 1995;73(3):277-283.

18. Nydegger A, Walsh A, Penny DJ, Henning R, Bines JE. Changes in resting energy expenditure in children with congenital heart disease. *Eur J Clin Nutr*. 2009;63(3):392-397.

19. Clemente C, Barnes J, Shinebourne E, Stein A. Are infant behavioural feeding difficulties associated with congenital heart disease? *Child: Care, Health and Development*. 2001;27(1):47-59.

20. Vaidyanathan B, Radhakrishnan R, Sarala DA, Sundaram KR, Kumar RK. What determines nutritional recovery in malnourished children after correction of congenital heart defects? *Pediatrics*. 2009;124(2):294.

21. Cohen MS, Zak V, Atz AM, et al. Anthropometric measures after fontan procedure: Implications for suboptimal functional outcome. *Am Heart J*. 2010;160(6):8, 1098.e1.

22. Medoff-Cooper B. Nutrition and growth in congenital heart disease: A challenge. *Current opinion in cardiology*. 2013;28(2):122-129.

23. Hartman D, Medoff-Cooper B. Transition to home after neonatal surgery for congenital heart disease. *MCN, The American Journal of Maternal/Child Nursing*. 2012;37(2):95-100.

24. American Academy oP. Breastfeeding and the use of human milk. *Pediatrics*. 1997;100:1035-1039.

25. Marino BL, O'Brien P, LoRe H. Oxygen saturations during breast and bottle feedings in infants with congenital heart disease. *Journal of Pediatric Nursing*. 1995;10(6):360-364.

26. Torowicz DL, Seelhorst A, Froh EB, Spatz DL. Human milk and breastfeeding outcomes in infants with congenital heart disease. *Breastfeeding Medicine*. 2015;10(1):31-37.

27. Imms C. Feeding the infant with congenital heart disease: An occupational performance challenge. *The American journal of occupational therapy: official publication of the American Occupational Therapy Association*. 2001;55(3):277-284.

28. Barbas KH, Kelleher DK. Breastfeeding success among infants with congenital heart disease. *Pediatric Nursing*. 2004;30(4):285.

29. Grummer-Strawn LM, Scanlon SC, Fein SB. Infant feeding and feeding transitions during the first year of life. *Pediatrics*. 2008; 122: S26-S42.

30. Breastfeeding report card united states/2016. National Center for Chronic Disease Prevention and Health Promotion. 2016.

31. Trabulsi JC, Irving SY, Papas MA, Hollowell C, Ravishankar C, Marino BS. Total energy expenditure of infants with congenital heart disease who have undergone surgical intervention. Pediatr Cardiol. 2015.

32. Kramer MS. Do breast-feeding and delayed introduction of solid foods protect against subsequent obesity? J Pediatr. 1981;98:883-887.

33. Koletsko B, von Kries R, Closa R, Escribano J, Scaglioni S, Giovannini M, et al. Lower protein in infant formula is associated with lower right at age 2y: a randomized clinical trial. *Am J Clin Nutr*. 2009;89:1836-45.

34. Dewey KG, Heinig MJ, Nommsen LA, Peerson JM, Lonnerdal B. Breast-fed infants are leaner than formula-fed infants at 1 y of age: the DARLING study. *Am J Clin Nutr*. 1993;57:140-5

35. Agostini C, Grandi F, Gianni ML, Silano M, Torcoletti M, Giovannini M et al. Growth patterns of breast fed and formula fed infants in the first 12 months of life: an Italian study. *Arch Dis Child*. 1999;8:395-399.

APPENDIX A

TABLES

Table A1- Demographic Characteristics of Infants and Parents

	N (%)
Infant Sex	
Male	33 (71.7)
Female	13 (28.2)
Infant Ethnicity	
Hispanic or Latino	4 (8.7)
Non-Hispanic or Latino	42 (91.3)
Infant Race	
White or Caucasian	37 (80.4)
Black or African American	6 (13.0)
Asian or Asian American	0 (0)
Native Hawaiian or Pacific Islander	0 (0)
Two or More Races	2 (4.3)
Other	1 (2.2)
Maternal Education	
11-12 y of high school	5 (10.9)
1-4 y of trade school	1 (2.2)
1-4 y of college	25 (54.3)
More than 4 y of college	15 (32.6)
Paternal Education	
12 y of high school	10 (21.7)
1-4 y of trade school	2 (4.3)
1-4 y of college	25 (54.3)
More than 4 y of college	9 (19.6)
Parental Age	**Mean±SD**
Maternal Age, y	31.0±5.0
Paternal Age, y	32.9±5.9

SD= standard deviation, y=years
NOTE: Data are preliminary, additional data are forthcoming.

Table A2- Infant Medical History at Two Weeks

CHD Diagnosis	**N (%)**
HLHS	20 (43.5)
TA	5 (10.9)
TGA-D	4 (8.7)
TOF	3 (6.5)
IAA	2 (4.3)
THAA	2 (4.3)
Complete TGA	2 (4.3)
TGA-L	1 (2.2)
DOR	1 (2.2)
DIL	1 (2.2)
PA	1 (2.2)
Single Ventricle	1 (2.2)
Pulmonary Vein Stenosis	1 (2.2)
TAPVR	1 (2.2)
Tricuspid Atresia	1 (2.2)

SD= Standard deviation, CHD= Congenital Heart Disease, HLHS= Hypoplastic left heart syndrome, TGA-L= Transposition of the great arteries-left, TOF= Tetralogy of Fallot, TA= Truncus arteriosus, DORV Double outlet right ventricle=, TGA-D= Transposition of the great arteries-right, IAA= Interrupted Aortic Arch, DILV= Double inlet left ventricle, THAA=Tubular hypoplasia of the aortic arch, PA= Pulmonary atresia, TAPVR= Total anomalous pulmonary venous return,
NOTE: Data are preliminary, additional data are forthcoming.

Table A3- Feeding Type and Mode for the First Four Months, by Month

	2 weeks (N=46)	**1 Month (N=46)**	**2 Months (N=46)**	**3 Months (N=45)**	**4 Months (N=45)**
Infant Age, days	14±4.4	29.9±5.6	63.7±6.6	97.4±11.0	128.7±9.8
Type of Feeding	N (%)	N (%)	N (%)	N (%)	N (%)
Fed BM only	29 (63.0)	16 (34.8)	15 (32.6)	15 (33.3)	14 (31.1)
BM fortified with formula	0	18 (39.1)	8 (17.4)	4 (8.9)	6 (13.3)
Mix of BM and formula	11 (23.9)	9 (19.6)	8 (17.4)	12 (26.7)	16 (35.6)
Formula only	6 (13.0)	3 (6.5)	15 (32.6)	14 (31.1)	9 (20.0)
Mode of Feeding					
Exclusive BF	0 (0)	1 (2.2)	3 (6.5)	4 (8.7)	4 (8.7)
Mix BF and bottle	6 (13.0)	12 (26.1)	17 (37.0)	12 (26.1)	8 (17.4)
Exclusive bottle	0 (0)	11 (24.0)	17 (37.0)	18 (39.1)	21 (45.7)
Mix bottle and NG	6 (13.0)	10 (21.7)	4 (8.7)	5 (10.9(	6 (13.0)
Exclusive NG feeding	2 (4.3)	5 (10.9)	4 (8.7)	5 (10.9)	4 (8.7)
Mix BF, bottle, NG	32 (70.0)	7 (15.2)	0 (0)	1 (2.2)	2 (4.3)

NOTE: Data are preliminary, additional data are forthcoming.

Table A4 – Anthropometry for the First Four Months, by Month

	Birth (N=46)	**2 Weeks (N=46)**	**1 Month (N=46)**	**2 Months (N=46)**	**3 Months (N=39)**	**4 Months (N=39)**
Infant Age, days	0	14±4.4	29.9±5.6	63.7±6.6	97.4±11.0	128.7±9.8
Average Z-Score						
Weight for Age Z-score	0.1±1.0	-0.5±1.5	-1.0±1.1	-1.1±1.1	-1.0±1.0	-1.2±1.0
Length for Age Z-score	0.04±1.2	-0.8±1.2	-1.0±1.1	-1.3±1.2	-1.1±1.3	-1.1±1.0
Head Circumference Z-score[1]	--	-1.1±1.2	-1.1±0.9	-1.1±1.2	-0.9±0.9	-1.6±4.1
Weight for Length Z-score	0.1±1.4	-0.1±1.7	-0.3±1.4	0.1±1.2	-0.2±1.2	-0.6±1.3

[1]Head circumference at birth not reported by parent. Data are preliminary, additional data are forthcoming.

Table A5 – Breastfeeding Patterns for the First Four Months

	N (%)
Feeding Pattern	
Principally BM	14 (30.4)
BM/Mix	18 (39.1)
BM/Mix/Formula	14 (30.4)

NOTE: Data are preliminary, additional data are forthcoming.

Table A6- Anthropometry Stratified by Feeding Pattern for the First Four Months of Life, by Month

	Birth (N=46)	2 Weeks (N=46)	1 Month (N=46)	2 Months (N=46)	3 Months (N=39)	4 Months (N=39)
Infant Age, days		14±4.4	29.9±5.6	63.7±6.6	97.4±11.0	128.7±9.8
Average Z-Score Principally BM						
Weight for Age Z-score	0.3±1.0	-0.2±2.0	-0.5±0.9	-0.7±1.0	-0.5±0.9	-0.9±1.0
Length for Age Z-score	-0.1±1.0	-0.5±1.0	-0.9±1.0	-1.0±0.9	-0.7±1.2	-1.1±0.9
Head Circumference Z-score[1]	--	-0.8±1.4	-0.1±0.5	-0.3±1.3	-0.2±0.8	-0.6±1.3
Weight for Length Z-score	0.4±0.9	0.5±2.4	0.4±1.4	0.4±1.2	0.1±1.3	-0.9±1.3
Average Z-Score BM, Mix						
Weight for Age Z-score	-0.2±1.2	-0.7±1.2	-1.2±1.1	-1.3±1.2	-1.4±1.1	-1.3±1.2
Length for Age Z-score	-0.0±1.3	-0.7±1.3	-1.1±1.3	-1.1±1.5	-1.2±1.3	-1.0±1.1
Head Circumference Zscore[1]	--	-1.3±1.3	-1.2±0.7	-1.1±1.4	-1.2±0.7	-0.7±1.1
Weight for Length Z-score	-0.2±1.6	-0.7±1.0	-0.6±1.1	-0.5±1.2	-0.7±1.3	-0.3±1.3
Average Z-Score BM, Mix, Formula						
Weight for Age Z-score	-0.1±0.9	-0.9±1.1	-1.2±1.1	-1.2±1.1	-1.2±0.8	-1.2±0.8
Length for Age Z-score	-0.1±1.4	-1.3±1.3	-1.0±0.9	-2.0±0.7	-1.3±1.3	-1.2±1.1
Head circumference Z-score[1]	--	-1.0±1.0	-1.5±1.0	-1.5±1.0	-1.2±0.9	-0.8±1.1
Weight for Length Z-score	0.1±1.3	-0.1±1.0	-0.6±1.6	0.7±1.0	-0.0±1.1	-0.1±1.1

[1]Head circumference at birth not reported by parent. Data are preliminary, additional data are forthcoming.

APPENDIX B

STUDY DOCUMENTS

B.1 Institutional Review Board Approval Letter

UNIVERSITY OF DELAWARE

RESEARCH OFFICE

210 Hullihen Hall
University of Delaware
Newark, Delaware 19716-1551
Ph: 302/831-2136
Fax: 302/831-2828

DATE:	August 5, 2016
TO:	Jillian Trabulsi, PhD
FROM:	University of Delaware IRB
STUDY TITLE:	[813477-2] Breastfeeding in Infants with Congenital Heart Disease
SUBMISSION TYPE:	Amendment/Modification
ACTION:	ACKNOWLEDGED
EFFECTIVE DATE:	August 5, 2016

Thank you for submitting the Amendment/Modification materials for the above research study. The University of Delaware IRB has ACKNOWLEDGED your submission. No further action on submission 813477-2 is required at this time.

The following items are acknowledged in this submission:

- Amendment/Modification - Amendment Form (UPDATED: 08/2/2016)
- Letter - Cover letter (UPDATED: 08/2/2016)
- Training/Certification - RCR certificate (UPDATED: 08/2/2016)
- Training/Certification - Human Subjects training (UPDATED: 08/2/2016)

If you have any questions, please contact Maria Palazuelos at (302) 831-8619 or mariapj@udel.edu. Please include your study title and reference number in all correspondence with this office.

B.2 Informed Consent Form

The Children's Hospital *of* Philadelphia®

Informed Consent Form and HIPAA Authorization

Study Title:	Breastfeeding the Infant with Congenital Heart Disease	
Version Date:	February 12, 2015	
Principal Investigator:	Rachelle Lessen, MS, RD, IBCLC, LDN	Telephone: 215-590-1089
Emergency Contact:	Rachelle Lessen, MS, RD, IBCLC, LDN	Telephone: 215-590-1089

You, or your child, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study principal investigator and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

Why are you being asked to take part in this study?

You are being asked to take part in this research study because you have an infant who was born with a congenital heart defect and you are or plan to breastfeed your infant.

What is the purpose of this research study?

The purpose of this study is to identify factors that affect breastfeeding in infants with congenital heart disease (CHD).

How many people will take part?

About 75 mothers and their infants will take part in this study.

What is involved in the study?

Should you agree to participate in this study, you will be interviewed once a month for the first 4 months of the study either in person or by telephone. After the 4 months, a study team member will contact you once every 2 months until your child is 12 months of age.

How long will you be in this study?

If you agree to take part, your participation will last for 12 months and will involve 9 study visits/telephone contacts.

What are the study procedures?

The study involves the following procedures.

Interviews: A member of the study team will collect information regarding your background which will include race, ethnicity and education. In addition, you will be asked if you are taking any medications. You will be asked to complete a questionnaire regarding your infant's feeding history and practices as well as medical history. Your infant's weight and length will be obtained from his/her medical record while you are inpatient at CHOP. We will ask about breastfeeding your infant and feeding your infant each month.

When your child is one year of age, we will contact your child's primary care provider to collect information from your child's medical record on growth (weight, length, and head circumference) during their first year of life. Throughout the study you will be asked to report if you think that anything bad has happened as a result of the study.

Visit/Contact Schedule

The table below provides a brief description of the purpose and duration of each study visit or contact.

Visit/contact	Purpose	Main Procedures	Duration
Visit 1, Week 1-2 or prior to hospital discharge	Screening visit	Informed Consent, Inclusion Criteria, Exclusion Criteria, General Interview Form, Demography, Infant Medical History, Infant Feeding History, Medications	1 hour and 30 minutes
Contact 2, Date of birth +30 days	Routine Interview	Monthly Infant Feeding Questionnaire, Maternal Medications	30 minutes
Contact 3, Date of birth +60 days	Routine Interview	Monthly Infant Feeding Questionnaire, Maternal Medications	30 minutes
Contact 4, Date of birth +90 days	Routine Interview	Monthly Infant Feeding Questionnaire, Maternal Medications	30 minutes
Contact 5, Date of birth +120 days	Routine Interview	Monthly Infant Feeding Questionnaire, Maternal Medications	30 minutes
Contact 6, Date of birth +180 days	Routine Interview	Monthly Infant Feeding Questionnaire, Maternal Medications	30 minutes
Contact 7, Date of birth +240 days	Routine Interview	Monthly Infant Feeding Questionnaire, Maternal Medications	30 minutes
Contact 8, Date of birth +300 days	Routine Interview	Monthly Infant Feeding Questionnaire, Maternal Medications	30 minutes
Contact 9, Date	Final Interview	Monthly Infant Feeding Questionnaire, Maternal Medications	30 minutes

of birth + 365 days of age		Growth Data (Weight, length, head circumference) from your child's first year of life will be obtained from your primary care provider	

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor. There is a risk for breach of confidentiality. The study team will make every effort to protect your and your infant's health care information.

Are there any benefits to taking part in this study?

We cannot guarantee or promise that you will receive any direct benefit by participating in this study. The knowledge gained from this research may help doctors and health care professionals determine how best to support mothers who breastfeed their infant with congenital heart disease.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record. Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

Can the principal investigator take you out of the study early?

The principal investigator may take you out of the study if:

- The study is stopped.
- You cannot meet all the requirements of the study.

What choices do you have other than this study?

There are options for you other than this study including:

- Not participation in this study.
- You may discuss other options available to you with your doctor.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from medical records and interviews. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

The identifiable information from this study will be destroyed 7 years after the study is completed. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, you must tell the investigator in writing.

Rachelle Lessen, MS, RD, IBCLC, LDN
The Children's Hospital of Philadelphia
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Additional Information

You will be informed if changes to the study are needed to protect your health. You will be told about any new information that could affect your willingness to stay in the study, such as new risks, benefits or alternative treatments.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

There are no additional costs for participating in this study.

Will you be paid for taking part in this study?

You will not receive any payments for taking part in this study.

Who is funding this research study?

The Division of Nursing at The Children's Hospital of Philadelphia is funding this research.

What if you have questions about the study?

If you have questions about the study, call the principal investigator, at 215-590-1089. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation and your participation. This study involves both the mother and the child. By signing this form you are consenting for both your participation as well as the participation of your child. You are also agreeing to let CHOP use and share your child's health information as explained above. If you don't agree to the collection, use and sharing of your child's health information, your child cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Subject (child)	Name of Subject (Mother)
Signature of Mother (18 years or older)	Date
Name of Authorized Representative to consent for child	Relation to subject: ☐ Mother
Signature of Authorized Representative (Mother)	Date

B.3 Inclusion/Exclusion Criteria Form

Inclusion/Exclusion Criteria

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ **Visit Date: __/__/__**

Inclusion Criteria:

Infant is ≥ 37 and ≤42 week gestation at birth	❒ Yes	❒ No
Infant is a singleton	❒ Yes	❒ No
Infant is appropriate for gestational age	❒ Yes	❒ No
Infant has been diagnosed with congenital heart disease	❒ Yes	❒ No
Infant has undergone or will undergo neonatal corrective or palliative surgery prior to discharge	❒ Yes	❒ No
Mother is ≥ 18 years of age	❒ Yes	❒ No
Mother is English speaking	❒ Yes	❒ No
Mother intents to breastfeed	❒ Yes	❒ No

Exclusion Criteria:

Infant does not have any other known anomalies which are known to affect feeding (cleft palate, craniofacial deformities, inborn errors of metabolism, etc.)	❒ Yes True	❒ No False

B.4 Infant Feeding History: Visit 1 at 2 Weeks Questionnaire

Infant Feeding History: Visit 1 at 2 weeks

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ Visit Date: __/__/__

This form is to be completed when subject is enrolled or prior to discharge

FEEDING INFORMATION

1. Has your child ever been breastfed? Yes No

If NO skip to question #2

About how long after delivery did you breast feed or try to breastfeed your baby for the very first time?

❒ Within first hour ❒ 1-12 hours ❒ 12-24 hours

❒ 24-36 hours ❒ 48-72 hours ❒ >72 hours

Where did you first breastfeed?

❒ SDU ❒ CICU ❒ Birth hospital ❒ Other_____

Was your infant breastfed prior to his/her first cardiac surgery? Yes No

Was your infant breastfed successfully after his/her first cardiac surgery? Yes No

While in the hospital did/has anyone helped you with breastfeeding by showing you how or talking to you about breastfeeding? Yes No

Who helped you with breastfeeding? (Check all that apply)

❒ Doctor ❒ Lactation Consultant ❒ Friend(s) ❒ Midwife

❒ Nurse ❒ Family Member(s) ❒ Other:_____

Using 1 to mean "Not at all helpful" and 5 to mean "Very helpful", how helpful was the breastfeeding help you received from a doctor, midwife, nurse or lactation consultant?

1 2 3 4 5

Infant Feeding History: Visit 1 at 2 weeks

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ Visit Date: __/__/__

Using 1 to mean "Disliked Very Much" and 5 to mean "Liked very much" how would you say you felt about breastfeeding during the first week you were breastfeeding?

1 2 3 4 5

Has your infant ever been test weighed to determine volume of milk consumed? Yes No

If so: Date: _____ Volume: _____ Location: Hospital Other: _____

Did you have any pain while breastfeeding at any time in the first 2 weeks? Yes No

Did you have any of the following problems breastfeeding your baby during your first 2 weeks of breastfeeding?

- ❒ My baby had trouble sucking
- ❒ My baby had trouble latching on
- ❒ I didn't have enough milk
- ❒ My baby choked
- ❒ My nipples were sore, cracked, or bleeding
- ❒ My baby wouldn't wake up to nurse regularly enough
- ❒ My breasts were overfull (engorged)
- ❒ My baby was not interest in nursing
- ❒ I had a yeast infection of the breast
- ❒ My baby got distracted
- ❒ I had a clogged milk duct
- ❒ My baby nursed too often
- ❒ My breasts were infected or abscessed
- ❒ It took too long for my milk to come in
- ❒ My breasts leaked too much
- ❒ I had trouble getting the milk flow to start
- ❒ I had some other problem
- ❒ My baby didn't gain enough weight
- ❒ My baby lost too much weight
- ❒ I had no problems

2. Were you ever able to hold your infant skin to skin?

If so, how old was your infant? _____ days

3. How long did it take for your milk to come in?

❒ 1 day or less ❒ 2 days ❒ 3 days ❒ 4 days ❒ More than 4 days

Infant Feeding History: Visit 1 at 2 weeks

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC, Jillian Trabulsi, PhD RD
Co-investigators: Chelsea Hollowell, Samantha Elliott
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ Visit Date: __/__/__

---

4. Has your child ever been formula fed? Yes No

How old was your baby when he or she was first fed formula?

❒ 1 day or less ❒ 2-6 days ❒ 7-13 days
❒ 14-20 days ❒ More than 20 days ❒ Never fed formula

Name of formula(s) _____

5. Have you previously breastfed with your other children? Yes No

6. Has your child ever received donor milk? Yes No

How old was baby when donor milk was started?

❒ 1 day or less ❒ 2-6 days ❒ 7-13 days

How many days did baby receive donor milk?

❒ 1 day ❒ 2 -4 days ❒ 5-7 days ❒ >7 days

7. Has your baby ever received a bottle? Yes No

How old was your baby when a bottle was first introduced?

❒ Within first hour ❒ 1-12 hours ❒ 12-24 hours
❒ 24-36 hours ❒ 48-72 hours ❒ >72 hours

8. Was your baby ever tube fed? Yes No

How old was the baby when the tube was first introduced? _____

9. How soon after birth did you first pump for your baby?

❒ 0-6 hours ❒ 6-12 hours ❒ 12-24 hours ❒ 24-48 hours ❒ >48 hours

What pump(s) did you use while your baby was in the hospital? _____

B.5 Monthly Infant Feeding Questionnaire- In Hospital

Monthly Infant Feeding Questionnaire – In hospital

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ Visit Date: __/__/__

FEEDING INFORMATION

1. **What is your baby currently feeding?**

   ❒ Breast milk only ❒ Breast milk fortified with powder formula ❒ Formula only ❒ Mix of breast milk and formula

   How many feedings per day? _____

   How many feedings from the breast? _____

   If not breastfeeding or feeding your breast milk: Skip to question # 9

2. **About how long does an average breastfeeding last?**

   ❒ Less than 10 minutes ❒ 20-29 minutes ❒ 40-49 minutes
   ❒ 10-19 minutes ❒ 30-39 minutes ❒ 50+ minutes

3. **In an average 24-hour period, what is the LONGEST time for you, the mother, between breastfeeding or expressing milk? Please consider both day and night time and begin the count from the start of one breastfeeding/expressing session to the start of the next.**

   _____ Hours AND _____ Minutes

4. **Are you currently receiving help with breastfeeding?** Yes No

   If so, from whom:

   ❒ Nurse ❒ Lactation Consultant ❒ Other:_____

5. **Has your infant been test weighed to determine volume of milk consumed?** Yes No

   If so: Date(s): _____ Volume: _____

6. **Are you currently feeding your infant a bottle?** Yes No

   How many feedings per day from the bottle? _____

Monthly Infant Feeding Questionnaire – In hospital

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ Visit Date: __/__/__

---

7. Are you currently feeding expressed breast milk in a bottle? Yes No

1. If yes, is it fortified? _____concentration_____
2. If yes, how much per feeding? _____
3. If yes, how often per day? _____
4. If yes, how many oz per day? _____

8. Are you currently pumping? Yes No

If so, how many times per day? _____

Daily milk production_____

Which pump are you using? _____

If you are no longer pumping, when and why did you stop? _____

_____

9. Are you currently using donor milk? Yes No Obtained from_____

10. Are you currently using formula? Yes No

If yes, name of formula? _____

If yes, how much per feeding? _____

If yes, how often per day? _____

If yes, how many oz per day? -_____

Concentration _____

11. If bottle feeding, how long does an average bottle feeding last?

- ❒ Less than 10 minutes
- ❒ 10-19 minutes
- ❒ 20-29 minutes
- ❒ 30-39 minutes
- ❒ 40-49 minutes
- ❒ 50+ minutes

12. Has your infant been fed via a nasogastric tube over the past month? Yes No

What percentage of feedings are via NG? _____

B.6 Monthly Infant Feeding Questionnaire- First Home Contact

Monthly Infant Feeding Questionnaire – First home contact

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ Visit Date: __/__/__

FEEDING INFORMATION

1. **When you left the hospital what were you feeding your baby?**

   ❒ Breast milk only ❒ Breast milk fortified with powder formula ❒ Formula only ❒ Mix of breast milk and formula

   a. Was your breast milk fortified at time of discharge? With what formula? _____

   b. Calorie concentration _____

2. **When you left the hospital how were you feeding your baby?**

   ❒ Breastfeeding only ❒ Breastfeeding and bottle feeding ❒ Breastfeeding and tube feeding

   ❒ Bottle feeding and tube feeding ❒ Tube feeding only ❒ Breastfeeding, bottle feeding and tube feeding

3. **Was your infant breastfed successfully before hospital discharge?** Yes No

4. **Were you given any information about breastfeeding support groups or services before you went home from the hospital?** Yes No

5. **What was your daily production at the time of discharge?**

   ❒ <250 ml/day ❒ 250-500 ml/day ❒ 500-750 ml/day ❒ >750 ml/day

6. **What was your peak daily milk production?**

   ❒ <250 ml/day ❒ 250-500 ml/day ❒ 500-750 ml/day ❒ >750 ml/day

   When was this?

   ❒ Week 1 ❒ Week 2 ❒ Week 3 ❒ Week 4

7. **What is your baby <u>currently</u> feeding?**

   ❒ Breast milk only ❒ Breast milk fortified with powder formula ❒ Formula only ❒ Mix of breast milk and formula

   How many feedings per day? _____

   How many feedings from the breast? _____

Monthly Infant Feeding Questionnaire – First home contact

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ Visit Date: __/__/__

If not breastfeeding or feeding your breast milk: Skip to question # 15

8. **About how long does an average breastfeeding last?**

   ❒ Less than 10 minutes ❒ 20-29 minutes ❒ 40-49 minutes
   ❒ 10-19 minutes ❒ 30-39 minutes ❒ 50+ minutes

9. **In an average 24 hour period, what is the LONGEST time for you, the mother, between breastfeedings or expressing milk? Please consider both day and night time and begin the count from the start of one breastfeeding/expressing session to the start of the next.**

   _____ Hours AND _____ Minutes

10. **Are you currently receiving help with breastfeeding?** Yes No

    If so, from whom:

    ❒ Breastfeeding Support Group ❒ Breastfeeding Class
    ❒ Lactation Consultant ❒ Other:_____

11. **Has your infant been test weighed to determine volume of milk consumed?** Yes No

    If so: Date(s): _____ Volume: _____

    Location: Home Hospital Other: _____

12. **Are you currently feeding your infant a bottle?** Yes No

    How many feedings per day from the bottle? _____

13. **Are you currently feeding expressed breast milk in a bottle?** Yes No

    1. If yes, is it fortified? _____concentration_____
    2. If yes, how much per feeding? _____
    3. If yes, how often per day? _____
    4. If yes, how many oz per day? -_____

14. **Are you currently pumping?** Yes No

    If yes, how many times per day? _____

    Daily milk production_____

    Which pump are you using? _____

    If you are no longer pumping, when and why did you stop? _____

_____

Monthly Infant Feeding Questionnaire – First home contact

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ **Visit Date: __/__/__**

---

15. Are you currently using donor milk? Yes No Obtained from _____

16. Are you currently using formula? Yes No

If yes, name of formula? _____

If yes, how much per feeding? _____

If yes, how often per day? _____

If yes, how many oz per day? -_____

Concentration_____

17. If bottle feeding how long does an average bottle feeding last?

- ❒ Less than 10 minutes
- ❒ 20-29 minutes
- ❒ 40-49 minutes
- ❒ 10-19 minutes
- ❒ 30-39 minutes
- ❒ 50+ minutes

18. If formula fed, how do you prepare your infant's formula?

Amount of powder _____ scoops

Amount of water _____ oz or cups (please circle one)

Do you add anything to your baby's bottle? Yes No

If *Yes*, what? _____

How much? _____

How often? _____

19. **In the past month, has your infant been hospitalized for any reason or has your baby been taken to a hospital for any outpatient procedure or surgery?** Yes No

How many nights was your baby in the hospital for the most recent problem since discharge after birth? _____ Nights

20. **Has your infant been fed via a nasogastric tube over the past month?** Yes No

What percentage of feeds are via the NG tube? -_____

B.7 Monthly Infant Feeding Questionnaire- All Other Home Contacts

Monthly Infant Feeding Questionnaire – all other home contacts

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ Visit Date: __/__/__

FEEDING INFORMATION

1. **What is your baby currently feeding?**

   ❒ Breast milk only ❒ Breast milk fortified with powder formula ❒ Formula only ❒ Mix of breast milk and formula

   How many feedings per day? _____

   How many feedings from the breast? _____

   If not breastfeeding or feeding your breast milk: Skip to question # 9

2. **About how long does an average breastfeeding last?**

   ❒ Less than 10 minutes ❒ 20-29 minutes ❒ 40-49 minutes
   ❒ 10-19 minutes ❒ 30-39 minutes ❒ 50+ minutes

3. **In an average 24 hour period, what is the LONGEST time for you, the mother, between breastfeedings or expressing milk? Please consider both day and night time and begin the count from the start of one breastfeeding/expressing session to the start of the next.**

   _____ Hours AND _____ Minutes

4. **Are you currently receiving help with breastfeeding? Yes No**

   If so, from whom: Breastfeeding Support Group Breastfeeding Class
   Lactation Consultant

   Other: _____

Monthly Infant Feeding Questionnaire – all other home contacts

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ **Visit Date: __/__/__**

---

5. **Has your infant been test weighed to determine volume of breastmilk consumed?** Yes No

   If so: Date(s):_____Volume:_____

6. **Are you currently feeding your infant a bottle?** Yes No

   How many feedings per day from the bottle? _____

7. **Are you currently feeding expressed breast milk in a bottle?** Yes No

   If yes, is it fortified? _____concentration_____

   If yes, how much per feeding? _____

   If yes, how often per day? _____

   If yes, how many oz per day? _____

8. **Are you currently pumping?** Yes No

   If so, how many times per day? _____

   Daily milk production_____

   Which pump are you using? _____

   If you are no longer pumping, when and why did you stop? _____

   _____

9. **Are you currently using donor milk?** Yes No Obtained from_____

10. **Are you currently using formula?** Yes No

    If yes, name of formula? _____

    If yes, how much per feeding? _____

    If yes, how often per day? _____

    If yes, how many oz per day? _____

    Concentration_____

Monthly Infant Feeding Questionnaire – all other home contacts

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ **Visit Date: __/__/__**

---

11. If bottle feeding how long does an average bottle feeding last?

❒ Less than 10 minutes ❒ 20-29 minutes ❒ 40-49 minutes

❒ 10-19 minutes ❒ 30-39 minutes ❒ 50+ minutes

12. If formula feeding, how do you prepare your infant's formula?

Amount of powder _____ scoops

Amount of water _____ oz or cups (please circle one)

Do you add anything else to your baby's bottle? Yes No

If *Yes*, what?_____

How much? _____

How often? _____

13. **In the past month, has your infant been hospitalized for any reason or has your baby been taken to a hospital for any outpatient procedure or surgery?** Yes No

How many nights was your baby in the hospital for the most recent problem since discharge after birth? _____ Nights

14. Has your infant been fed via a nasogastric tube over the past month? Yes No

What percentage of feedings are via NG?_____

15. Has your child received any solid foods? Yes No

B.8 Demography Questionnaire

Demography: Visit 1

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ Visit Date: __/__/__

DEMOGRAPHIC QUESTIONNAIRE

QUESTIONS ABOUT MOM

How many years of schooling have you had? (Circle the last grade completed.)

Grade School: 1 2 3 4 5 6 7 8

High School: 9 10 11 12

Trade School: 1 2 3 4

If a trade school, how long was the program in years or months? _____

College/University: 1 2 3 4 (Name of college: _____)

Graduate education (Master's or Doctoral Degree):_____

Do you have a job in addition to being a mother? YES NO

If yes, what kind of work do you do? _____

_____

QUESTIONS ABOUT THE CHILD'S FATHER

How many years of schooling has your child's father had? (Circle the last grade completed.)

Grade School: 1 2 3 4 5 6 7 8

High School: 9 10 11 12

Trade School: 1 2 3 4

- If a trade school, how long was the program in years or months? _____

College: 1 2 3 4 (Name of college: _____)

Graduate education (Master's or Doctoral degree):_____

What is your child's father's occupation? _____

Do you currently participate in federal nutrition education programs such as WIC? Yes No

If so, but it is not WIC, please specify the name: _____

Demography: Visit 1

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ Visit Date: __/__/__

If not participating presently, have you participated in the past? Yes No

If yes, when did you participate (dates)? _____

_____

What is YOUR (Mother) ethnic category?

- ❑ Hispanic or Latino
- ❑ Not Hispanic or Latino

What is YOUR (Mother) racial background? (*Check all that apply*)

- ❑ White or Caucasian
- ❑ Black or African American
- ❑ American Indian or Alaskan Native
- ❑ Asian or Asian American
- ❑ Native Hawaiian or Pacific Islander
- ❑ Other (*please specify*) _____

What is YOUR CHILD'S FATHER'S ethnic category?

- ❑ Hispanic or Latino
- ❑ Not Hispanic or Latino

What is YOUR CHILD'S FATHER'S racial background? (*Check all that apply*)

- ❑ White or Caucasian
- ❑ Black or African American
- ❑ American Indian or Alaskan Native
- ❑ Asian or Asian American
- ❑ Native Hawaiian or Pacific Islander
- ❑ Other (*please specify*) _____

What is YOUR CHILD'S ethnic category?

- ❑ Hispanic or Latino
- ❑ Not Hispanic or Latino

Demography: Visit 1

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ Visit Date: __/__/__

What is YOUR CHILD'S racial background? (*Check all that apply*)

- ❑ White or Caucasian
- ❑ Black or African American
- ❑ American Indian or Alaskan Native
- ❑ Asian or Asian American
- ❑ Native Hawaiian or Pacific Islander
- ❑ Other (*please specify*) _____

B.9 General Interview Questionnaire

General Interview Form: Visit 1

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC, Jillian Trabulsi, PhD RD
Co-investigators: Chelsea Hollowell, Samantha Elliott
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ Visit Date: __/__/__

GENERAL INTERVIEW FORM- VISIT 1

Interviewer Initials: _____

I will be asking you a number of questions about yourself and your child. Some of the questions may seem fairly personal, so I'd like you to keep in mind that we administer the same questionnaire to every subject in this study, all of the information is relevant to the research we are doing, and everything you tell me is strictly confidential.

QUESTIONS ABOUT MOM

1. **What is your (Mom's) date of birth?**

   _____**Age:**_____

2. **Are you single, divorced, widowed, or married?** _____

3. **What is the date of birth of the child to be enrolled?**

   _____

4. **What is the gender of the child to be enrolled in this study?** ♀ ♂

5. **How many children do you have?**_____

6. **What is the age and gender of your other children?** age_____gender ♀ ♂

   age_____gender ♀ ♂ age_____gender ♀ ♂

   age_____gender ♀ ♂ age_____gender ♀ ♂

8. **What is the birth order of the child currently enrolled in the study?** _____

9. **Please list the relation and ages of EVERYONE, including yourself, other adults and other children, PRESENTLY LIVING IN YOUR HOME. (Do not use names, only their relation to you (i.e. mother, father, husband, son, daughter, etc.)**

RELATION:	**AGE:**	**SMOKER? (Yes / No)**
Self		

General Interview Form: Visit 1

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC, Jillian Trabulsi, PhD RD
Co-investigators: Chelsea Hollowell, Samantha Elliott
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ Visit Date: __/__/__

_____ _____ _____
_____ _____ _____
_____ _____ _____

10. **Your (Mom's) height:** _____ ft. _____ in.

    Your (Mom's) weight: _____lbs.

QUESTIONS ABOUT THE CHILD'S FATHER

11. **How old is your child's father?** _____
    How tall is he? _____ How **much does he weigh?** _____

12. **What is the best method to contact you for study updates, reminders, scheduling, etc.? Please provide all information, and check which you prefer:**
    - ❑ Telephone contact information
    - ❑ Home _____
    - ❑ Cell _____
    - ❑ Work _____
    - ❑ Which do you prefer for contact
      - o Home
      - o Cell Phone

      _____
    - ❑ Email: _____

B.10 Infant Medical History Questionnaire

Infant Medical History- Visit 1

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ Visit Date: __/__/__

---

1. **What was your infant's congenital heart disease diagnosis?**

❒ Hypoplastic left heart syndrome
❒ Valvular pulmonary atresia
❒ Double inlet left ventricle
❒ L-Transposition of great arteries
❒ D-transposition of great arteries
❒ Tetralogy of fallot
❒ Double outlet right ventricle
❒ Interrupted aortic arch
❒ Coarctation of the aorta
❒ Total anomalous pulmonary venous return
❒ Truncus arteriosus
❒ Valvular septal defect
❒ AP Window
❒ Other: _____

2. **What was your infant's gestational age?** _____ weeks

3. **What was your infant's birth weight?** _____kg

4. **What was your infant's birth length?** _____cm

5. **What is your infant's medical history? (other diagnoses besides congenital heart disease)**

_____
_____
_____
_____

6. **What is your infant's surgical history?**

Describe: _____ Date: _____

Describe: _____ Date: _____

Describe: _____ Date: _____

B.11 Maternal Medications Questionnaire

Maternal Medications

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ Visit Date: __/__/__

Medications- Breastfeeding Mothers

Are you taking any medications or have you taken any in the past month? *If yes, please record below:*			Yes No
Medication Name: Reason:	____/_____/_____ MM / DD / YYYY	_____/_____/_____ MM / DD / YYYY	*Circle one of options below:* Prophylactic Use Treatment for _____
Medication Name: Reason:	____/_____/_____ MM / DD / YYYY	_____/_____/_____ MM / DD / YYYY	*Circle one of options below:* Prophylactic Use Treatment for _____
Medication Name:	____/_____/_____ MM / DD / YYYY	_____/_____/_____ MM / DD / YYYY	*Circle one of options below:* Prophylactic Use Treatment for _____
Reason:			