BREASTFEEDING INFANTS
WITH CONGENITAL HEART DISEASE

by

Rachel R. Rickman

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Rachel R. Rickman

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
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Congenital Heart Disease (CHD) is the most common birth defect in the world and is the leading cause of infant mortality. Many infants with CHD have significantly poor growth which is concerning, since poor nutrition can affect length of hospital stay, immune function, wound healing, and neurodevelopment. Poor nutritional status likely stems from a multitude of reasons including feeding schedule interruption due to medical procedures and surgery, difficulties with feeding (poor suck, tiring out easily during a feeding), and increased energy expenditure prior to heart defect repair. In the past, it was recommended that CHD infants receive infant formula from a bottle, the thought being that breastfeeding was too physiologically taxing for the CHD infant. With that theory disproven, and with increasing knowledge of the nutritional benefits of breastmilk, breastmilk is recommended for all infants, healthy or with chronic disease/illness. Breastmilk is the gold standard of feeding for infants, but the course and success of breastmilk feeding/breastfeeding among infants with CHD throughout the first year of life is unknown. In this observational study, we sought to determine the incidence of breastmilk feeding/breastfeeding among infants with CHD throughout the first 12 months of life. Second, we sought to assess the exclusivity of breastmilk feeding/breastfeeding and factors that affect breastmilk feeding/breastfeeding.
To date, a total of 43 of the target 75 mother-infant dyads were recruited to participate in this study from the Cardiac Intensive Care Unit at the Children’s Hospital of Philadelphia. Thirty-four of these infants completed the 3-month visit and 23 infants completed the 6 month-visit. We found that 95% of infants were reported to have been fed any breastmilk at 1 month, 73.5% at month 3, and 52.2% at month 6. In contrast, the incidence of infants receiving only infant formula increased over the 6 months, from only 5.1% at month 1 to 47.8% at month 6. There was no significant difference in duration or exclusivity of breastmilk feeding/breastfeeding in infants who were only hospitalized once versus infants who were re-hospitalized more than once. There was no significant difference in duration of breastmilk feeding/breastfeeding duration in infants who were fed via an enteral tube versus those who were not. As the study continues, we will have the data to examine other factors that may impact breastfeeding exclusivity and duration, such as weight gain and growth. The results presented in this thesis are preliminary and will be repeated when the data set is complete.
Chapter 1

INTRODUCTION

Congenital Heart Disease (CHD) is an abnormality of the heart and/or large vessels that occurs during fetal development; it is the most common birth defect in the world, with an incidence of 1%\(^1\). In the United States, CHD occurs with an incidence of 8 per 1,000 births\(^2\) and is also the leading cause of infant mortality\(^3,4\). Mortality rates differ by race, non-Hispanic black infants with CHD have higher mortality rates than non-Hispanic white infants with CHD\(^5\). A majority of infants with CHD undergo medical or surgical intervention within the first 30 days of life\(^6\). Approximately 95% of the babies born with a non-critical CHD are expected to survive to 18 years of age compared to 69% of infants with critical CHD\(^6\).

Poor growth and malnutrition are concerns for many parents of infants with CHD; almost half of infants two years or younger with CHD have stunted growth when compared to non-CHD controls\(^7\). Several studies have reported infants with CHD have lower than normal weight for age, weight for length, and length for age z-scores\(^8-10\). Poor growth is a concern as it has been shown to result in longer hospital stays and negatively affect developmental outcomes\(^7,11\). Feeding infants with CHD can be more challenging than feeding healthy infants. Mothers of infants with CHD report many different feeding difficulties for their infants such as choking, swallowing dysfunction, and tiring more easily during a feed than normal infants\(^13\) and these
feeding problems can lead to insufficient nutrient intake. Infants with CHD are more likely to be bottle fed as the first feeding method compared to non-CHD infants who are more likely to be breast fed as the first feeding method. While breastmilk is considered the best method for feeding all infants, there is little evidenced based information on the course of breastfeeding and successful breastfeeding practices in contemporary infants with CHD.
2.1 Congenital Heart Disease

Congenital heart disease (CHD) is defined as a malformation of the heart, aorta, or large blood vessel that disrupts the normal physiology and blood flow of the heart\(^1\). In individuals with normal cardiac structure, blood enters the right atrium through the superior vena cava, travels through the tricuspid valve and into the right ventricle. Next, blood flows into the lungs through the pulmonary artery where it becomes oxygenated and re-enters the heart through the pulmonary vein into the left atrium. Finally, blood flows into the left ventricle through the mitral valve where it is pumped into the aorta and travels throughout the body providing oxygen rich blood to tissues and organs, before eventually returning to the heart via the superior vena cava\(^1\)\(^4\).

In infants with CHD, defects can be categorized as either acyanotic or cyanotic. Acyanotic defects consist of a left to right shunt (where oxygenated blood from the left side of the heart flows into the right side through a hole), or an obstructive lesion (in which there is a blockage of blood flow resulting in a build-up of pressure)\(^1\)\(^5\). Cyanotic defects consist of shunts from the right side of the heart to the left, resulting in sending un-oxygenated blood being delivered to the body. CHD can
be diagnosed either in utero via an electrocardiogram (EKG) or soon after birth when symptoms arise via an echocardiogram (ECG)\textsuperscript{16}. These procedures are commonly used to identify problems with the heart structure or incorrect blood flow.

**2.1 Acyanotic Defects**

Acyanotic congenital heart lesions involve a hole in the heart and shunting of blood from the left heart to the right heart; they most typically include atrial septal defect (ASD), ventricular septal defect (VSD), and patent ductus arteriosus (PDA). Acyanotic lesions often result in increased pulmonary blood flow\textsuperscript{15}.

**2.1.1 Atrial Septal Defect**

Atrial Septal Defect (ASD) is a birth defect in which the heart has a hole in the septum that divides the atria resulting in blood flowing back and forth between the right and left atrium\textsuperscript{14}. This hole increases the amount of blood that flows into the lungs over time and can lead to blood vessel damage, which in turn can lead to adulthood high blood pressure, increased risk of stroke, or heart failure. It has been estimated that about 1,966 babies in the United States each year are born with ASD\textsuperscript{17}.

**2.1.2 Ventricular Septal Defect**

Ventricular Septal Defect (VSD) is the most common acyanotic defect and is identified by a hole in the interventricular septum. This results in blood traveling
through a hole from the left ventricle to the right ventricle, sending increased blood volume to the lungs, which can lead to pulmonary congestion\textsuperscript{15}.

### 2.1.1.3 Patent Ductus Arteriosus

Patent Ductus Arteriosus (PDA) is a heart defect in which there is a hole in the aorta resulting in blood flowing from the aorta into the pulmonary artery and away from the lungs. This leads to increased work and strain on the heart and lungs, pulmonary congestion, and breathing difficulty for the infant. If the PDA is small, it can correct itself over time and does not require surgery; however, if the PDA is large a surgical procedure is performed to close the hole\textsuperscript{18}.

### 2.1.2 Cyanotic Defects

Cyanotic congenital heart defects occur when un-oxygenated blood from the right side of the heart enters the systemic circulation, resulting in cyanosis (babies tend to turn blue from a lack of oxygen in the blood). Cyanotic defects include interrupted aortic arch, pulmonary atresia, transposition of the great arteries, and hypoplastic left heart syndrome, to name a few. Infants born with a cyanotic defect require surgical intervention as soon as possible\textsuperscript{15}.

#### 2.1.2.1 Interrupted Aortic Arch

Interrupted Aortic Arch (IAA) occurs when there is a missing a portion or discontinuation of the aortic arch; these infants also commonly present with a large
VSD. Infants with IAA are usually pale, mottled and cool, and often present with weakness, poor feeding, low blood oxygen saturation and a decreased urine output\textsuperscript{14}.

\subsection*{2.1.2.2 Pulmonary Atresia}

Pulmonary Atresia (PA) is a defect where the infant is born with no pulmonary valve. As a result, blood cannot flow from the right ventricle into the pulmonary artery and eventually lungs for oxygenation. In addition, the right ventricle and tricuspid valve are poorly developed and there is an opening in the atrial septum that allows the blood to exit the right atrium and enter the left atrium, resulting in the mixing of low-oxygenated blood with oxygen-rich blood. The left ventricle then pumps this mixture of under-oxygenated blood into the aorta and out into the body\textsuperscript{15}.

\subsection*{2.1.2.3 Transposition of the Great Arteries}

Transposition of the Great Arteries (TGA) occurs when the two main arteries carrying blood out of the heart, the main pulmonary artery and the aorta, are switched or transposed. This results in un-oxygenated blood being pumped from the right side of the heart into the aorta where it then enters the body instead of the lungs as in a normal heart. Oxygen-rich blood from the lungs enters the heart through the pulmonary veins but is then pumped back into the lungs through the pulmonary artery\textsuperscript{14}.
2.1.2.4 Hypoplastic Left Heart Syndrome

Hypoplastic Left Heart Syndrome (HLHS) is a birth defect in which the normal blood flow is disrupted because of a poorly developed left side of the heart\textsuperscript{14}. The left ventricle, ascending aorta, and mitral valves are all underdeveloped or not developed at all in infants with HLHS. These infants also may have an atrial septal defect allowing oxygenated blood to flow into the right atrium instead of out into the body. The combined effect of these deformities is the inability to pump oxygen-rich blood to the body and poor tissue oxygenation\textsuperscript{15}.

2.1.2.5 Tetralogy of Fallot

Infants born with Tetralogy of Fallot (TOF) have four defects of the heart and blood vessels. These defects include Ventricular Septal Defect (a hole in the septum between the two ventricles), Pulmonary Stenosis (a narrowing of the pulmonary valve and main pulmonary artery), Right Ventricular Hypertrophy (thickened muscle wall of the right ventricle) and lastly an enlarged aortic valve that opens from both ventricles instead of just from the left ventricle as in a normal heart. As a result, the normal amount of blood is prevented from being pumped into the lungs which can cause cyanosis and shortness of breath\textsuperscript{14}.

2.1.3 Single Ventricle and Biventricular Physiologies

Congenital Heart Disease can also be classified by not only being cyanotic or acyanotic, but also as having a single ventricle or biventricular structure of the heart.
Infants that have a single ventricular structure only have one ventricle, right or left that is fully functioning. Single ventricle defects are rare as they occur in 5 of every 100,000 live births. The single ventricle becomes extremely overworked, blood flow and oxygenation in the lungs is hampered, and the infant’s skin eventually appears a bluish color which indicates poor blood oxygenation\textsuperscript{19}.

\subsection{2.1.4 Surgical Procedures}

Surgical intervention is common for many infants with CHD. If the defect results in critical lack of oxygen, such as cyanotic defects, surgery occurs within the first days of life. For infants with less severe defects, the surgery can take place in the first few weeks of life. Surgical procedures such as catheter procedures can correct simple defects and are commonly used for septal defects, or stenosis, in which a hole is closed or a valve is pushed open\textsuperscript{20}. Open-heart surgery is still common for many infants with a cyanotic CHD, and especially for infants with multiple defects. Cardiac surgeries can either be described as a reparative heart surgery, used to correct the heart defect, or a palliative heart surgery, used to relieve the symptoms but not fully correct the heart defect\textsuperscript{21}. An example of palliative procedures is a three-stage reconstruction for infants with HLHS. First, the modified Norwood procedure is used to create a false aorta; then within a year infants undergo a second procedure called the Glenn shunt that creates a passive pulmonary blood flow; and finally, at the age of three, the child has a third surgery that completely separates the pulmonary and the systemic blood flow systems\textsuperscript{8}. 
Infants with CHD have many challenges post-surgery ranging from infections to difficulties with feeding, all of which can be extremely stressful on the parent(s) and infant. Infants with CHD commonly have difficulties with weight gain between surgical intervention and discharge even with the help from supplemental feeding devices. The length of stay in the hospital for infants with CHD depends not only on whether surgery is required or not, but also the type of CHD. It has been reported that infants with a cyanotic CHD stay twice as long in the hospital before being discharged, and this can significantly impact feeding. Complex medical issues and surgeries commonly faced by infants with cyanotic defects can result in a postponement of breastfeeding initiation when compared to infants with acyanotic defects.

2.2 Feeding Infants with CHD Post Surgery

At times, breastfeeding has been misconstrued to mothers of infants with CHD as impossible or worthless. The reality is that breastfeeding is the gold standard for feeding all infants, healthy or ill. Unfortunately, some mothers of infants with CHD have reported that they receive little to no encouragement from hospital staff regarding breastfeeding their infant with CHD. In a six-month longitudinal study following 62 mothers and their infants with CHD who had recent surgery, mothers initially reported feeling as though doctors and nurses encouraged them to use formula rather than attempt breastfeeding. As the study progressed, mothers reported that they were increasingly given more information and help with breastfeeding and pumping.
breastmilk. When discharged from the hospital post-surgery, 45 mothers (72%) reported they were able to increase the frequency that they breastfed their infant, and 85.3% of mothers continued breastfeeding at three months, and 64.7% continued breastfeeding at five months. Data from the same hospital, 10 years earlier, found that 57% of mothers continued breastfeeding at three months, and 48% at five months. This data shows that there has been a significant increase in breastfeeding rates for infants with CHD in recent years.

2.3 Growth of Infants with CHD

Once at home, a significant stressor for families of infants with CHD is the feeding and growth of the infant. Infants with CHD infants have been known to grow poorly in infancy and continue this poor growth through adolescence\textsuperscript{24,25,27}. Most infants with CHD are born at a normal weight for gestational age but have been shown to develop growth problems and have poor nutrition during infancy\textsuperscript{28,29}. One study found that 50% of infants who underwent surgical intervention showed inadequate growth while 30% fell below the third percentile\textsuperscript{30}. It was also reported that CHD infants were significantly lower in weight and weight-for-age z-scores at 3-months when compared with healthy controls\textsuperscript{31}.

It has been suggested that increased total energy expenditure (TEE), due to strain on the heart or due to recovery from surgery, is one factor that contributes to poor growth in infants with CHD. TEE in infants with CHD who have not undergone surgical intervention is often elevated when compared to healthy infants\textsuperscript{32,33}; once the
infant with CHD undergoes surgical intervention, it appears that they have a similar TEE to that of the healthy control infants\textsuperscript{34,35}. As such, it has been suggested that poor energy intake may be another factor contributing to poor growth in infants with CHD\textsuperscript{36,37}.

The mode of feeding, breastfeeding versus bottle-feeding has been shown to affect growth. One study found that CHD infants who were fed breastmilk/breastfed gained weight more quickly and also had shorter hospital stays than formula/bottle-fed CHD infants\textsuperscript{38}. In addition, it was also found that infants with CHD who were formula/bottle-fed fell significantly further off the growth curve than the infants with CHD who were being fed breastmilk/breastfeeding\textsuperscript{38}. This leads to the conclusion that breastmilk/breastfeeding leads to sufficient and perhaps improved growth of infants with CHD compared formula feeding. However, breastfeeding/feeding breastmilk can be challenging for mothers of infants with CHD.

2.4 Feeding Practices of Infants with CHD

Feeding breastmilk, either via bottle or directly from the breast, is considered the gold standard and most beneficial practice for feeding all infants\textsuperscript{26}. Families of infants with CHD transition to home, they have reported anxiety over their infant’s feeding practices, health, uncertainty about the child’s survival, and worries about weight gain and growth\textsuperscript{39,40}. A study by Hartman & Medoff-Cooper (2012) followed primary caregivers of infants with CHD in the first three months after hospital discharge and found that caregivers reported many difficult problems with feeding.
Caregivers reported that bottle fed infants would cease eating quickly after beginning and would barely consume any calories. Infants that were being tube fed were reported to feed better than bottle fed babies, and these caregivers reported less worry about caloric intake but had to worry more often about the baby taking out the feeding tube. Despite caregivers having different feeding management, almost every infant had a vomiting issue. Caregivers felt frustrated that the infants were not keeping the calories they so badly needed and noticed their infants had weight loss instead of weight gain. Many reported that the infants gave no verbal or nonverbal cues that they were hungry or full leading to feeding when the infant was not hungry and to over eating resulting in vomiting. Anxiety was a common word used to express how they felt about making sure their baby gained weight, and that it was constantly on their mind.25

Some infants with CHD have poor oral skills and intake from breast or bottle is insufficient, therefore they must be tube fed41. With long-term successful maintenance of tube feeding, infants with CHD were found to meet appropriate growth compared to CHD infants that were not tube fed42. Although nasogastric (NG) tube feeding can provide an infant with supplemental energy, there are disadvantages and complications. Some of the complications with NG feeding include impairment of oral feeding and dislocation of the NG tube which requires new placement43.

2.5 Breastfeeding Infants with CHD

The American Academy of Pediatric recommends all infants be breastfed exclusively for the first six months of life, with continued breastfeeding combined
with complementary foods until 12 months of age\textsuperscript{26}. However, the most common feeding method for infants with CHD has been reported to be bottle-feeding\textsuperscript{12}. In a prospective cohort study of 110,000 pregnant Norwegian women and their children, the prevalence of breastfeeding among infants with CHD compared to the general population of healthy infants\textsuperscript{44}. At 6 months of age, mothers of healthy control infants were more likely to report breastfeeding than mothers of infants with CHD, 69.1\% and 64.1\% respectively. Also at 6 months, 14.7\% of control infants were predominately breastfeeding compared to 9.9\% of infants with CHD, meaning that mothers of infants with CHD were supplementing breastmilk with infant formula or other food. For infants with CHD and other co-morbidities, the incidence of breastfeeding at 6 months was 43.1\% with only 7.7\% predominately breastfeeding. Infants with CHD and other co-morbidities were also more the likely to be weaned earlier compared to the healthy control group.

Efforts are in place to try to improve breastfeeding rates among infants with CHD. For example, in a recent study women giving birth at the Children’s Hospital of Philadelphia Special Delivery Unit were given information about breastfeeding and pumping breastmilk before giving birth to their CHD infant\textsuperscript{45}. Even if these women had no prior intention of pumping or breastfeeding they were more likely to initiate either breastfeeding or pumping breastmilk after giving birth compared to women who received no or less information elsewhere (96\% and 67\% respectively). This study led the authors to conclude that when women of CHD infants are given information, encouragement, and help to initiate lactation and breastfeeding, they are more likely to
do so. The importance of the institutional culture of breastfeeding cannot be over
looked, hospitals and other delivery centers are the first step to increasing
breastfeeding rates.

2.5.1 Obstacles in Breastfeeding Infants with CHD

Multiple studies have reported that mothers of infants with CHD often face more
barriers when breastfeeding than mothers of healthy infants\textsuperscript{12,13,27}. For example,
mothers of healthy infants reported that they did not breastfeed their infant for
personal reasons while mothers of infants with CHD reported that they did not
breastfeed their infant because of a problem with breastfeeding\textsuperscript{12}. Mothers of infants
with CHD were more likely to adjust their infant’s diet in hopes of helping their infant
gain weight and grow\textsuperscript{25}.

There is a need for parental support in the early stages as many parents have
reported stress about lengthy feedings, over consumption that leads to infant vomiting,
worry about weight gain, and anxiety of infant growth\textsuperscript{25}. Parents of infants with CHD
reported being more intense and serious during feeding time compared to parents of
healthy infants\textsuperscript{12}.

2.5.2 Breastfeeding Success of Infants with CHD

Historically, mothers of infants with CHD were encouraged to bottle feed as opposed
to breastfeed their infant as it was thought that breastfeeding was more stressful for the
infant\textsuperscript{27,38}. However, a study conducted by Marino, et al. (1995) provided evidence
that this may not be the case. In this study, oxygen saturation concentrations were measured continuously in infants with CHD who were either breastfed or bottle-fed. No breastfed infant desaturated (showed lower oxygen saturation) but four of the seven bottle-fed infants desaturated during phases of vigorous sucking. This study was one of the first to suggest that breastfeeding does not impart physiologic stress to the infant with CHD and that bottle-feeding may be more strenuous and more “work” for these infants.

There has been a very recent interest in encouraging mothers of infants with CHD to breastfeed. In one study, mothers were given a 6-month intervention which provided information and help on how to cope with their child’s diagnosis and how to strategize in order to optimize feeding success. This study found a significant difference between the intervention and control group’s level of stress. The mothers who underwent the intervention reported a reduction in their level of anxiety and worry and an increase in their use of positive strategies to cope with issues at hand.

The prevalence of breastfeeding infants with CHD is lower than the general population and this is thought to be due to the barriers and obstacles that parents encounter such as hospitalizations, surgical procedures, illness, and a lack of support. While the prevalence of breastfeeding in this population has increased over the past decade, there is little contemporary data on breastfeeding exclusivity and duration in infants with CHD, and the course of breastfeeding for such infants.
Chapter 3

AIMS

The overall aim of this proposal is to describe breast feeding practices and identify factors that affect breastfeeding duration and exclusivity in infants with congenital heart disease (CHD) in a prospective, observational study.

3.1 Specific Aims

Specific Aim 1: Describe breast feeding practices in the first six months of life in infants with CHD. Because infants with CHD have feeding difficulties such as choking, swallowing dysfunction, and since they tire more easily during a feed than normal infants\textsuperscript{13}, we hypothesize that the rates of feeding breastmilk/breastfeeding will be lower than normal healthy infants from birth to 6 months.

Specific Aim 2A: Assess duration of feeding breastmilk/breastfeeding in infants with CHD who had no re-hospitalizations after original discharge from the hospital from birth to 6 months of age compared to those who had one or more re-hospitalizations after discharge. Because mothers of infants with CHD who have undergone surgical procedures and re-hospitalizations report more stress and frequent medical complications\textsuperscript{24}, we hypothesize that infants with multiple re-hospitalizations will have a higher incidence of switching to formula as opposed to breastmilk or mixed feeding as a result of stress from the mother.
Specific Aim 2B: Assess duration of exclusive breastmilk feeding/breastfeeding in infants with CHD who had no re-hospitalizations after original discharge from the hospital from birth to 6 months of age compared to those who had one or more re-hospitalizations after discharge. Because mothers of infants with CHD who have undergone surgical procedures and re-hospitalizations report more stress and frequent medical complications\textsuperscript{24}, we hypothesize that infants with multiple re-hospitalizations will have a higher incidence of mixed feedings versus exclusive breastmilk feedings and shorter duration of breastfeeding/feeding of breastmilk.

Specific Aim 3: Assess duration of breastmilk/breastfeeding of infants with CHD who have received enteral tube feeding versus those who have not. Since infants with CHD fed via an NG tube were more likely to achieve appropriate growth when compared to CHD infants that were not tube fed\textsuperscript{42}, we hypothesize that infants who receive enteral tube feedings will be fed breastmilk/breastfeed for a longer duration because the mother is less worried about growth.
Chapter 4

METHODS

4.1 Subject Recruitment and Informed Consent

The protocol, procedures, and questionnaires for this study were reviewed and approved by the Institutional Review Board (IRB) at the Children’s Hospital of Philadelphia (CHOP) prior to study initiation; the University of Delaware (IRB) also reviewed and approved this study. Approximately 75 subject pairs of mother-infant dyads are planned to participate in this on-going study. Mother-infant dyads are being recruited from the Cardiac Intensive Care Unit at the Children’s Hospital of Philadelphia.

To be eligible to participate in the study, the inclusion criteria specified that: at birth infants must be at term (≥37 and ≤42 week gestation at birth), singleton, appropriate for gestational age infant, at time of enrollment infants must have been diagnosed with congenital heart disease (CHD), must have undergone or will undergo neonatal corrective or palliative surgery prior to discharge, infant must be age 0-21 days, mother must be ≥ 18 years of age, mother must be English speaking and mother must be planning to breastfeed. Exclusion criteria were: any other known physical, neurological, or physiologic anomalies, which are known to affect feeding (e.g. cleft
palate, inborn errors of metabolism) or a congenital heart defect not requiring surgical repair.

4.2 Study Visit Procedures

The Principal Investigator identifies potential subjects from the Cardiac Intensive Care Unit (CICU) and asks potentially eligible parents if they are interested in participating in a study of breastfeeding infants with CHD. If yes, the first study visit is scheduled and the informed consent process is initiated; once the IRB approved inform consent form is signed by the mother, the mother-infant dyad is assigned subject numbers and listed on the Subject Master List. Next, the mother-infant dyad is screened for inclusion/exclusion criteria and if the dyad meets the criteria, they are enrolled into the study. If the dyad did not comply with the criteria they are defined as a screening failure and the reason for such is recorded on the Subject Master List.

Once enrolled, the first visit includes the following questionnaires: a parent/infant demography questionnaire, general interview questionnaire, infant medical history questionnaire, and infant feeding history questionnaire. After the initial visit, all remaining study visits include a monthly infant feeding questionnaire and a maternal medication questionnaire.

4.3 Anthropometry Measurements

While the infant is inpatient, the weight and length are obtained from the medical record. After discharge from the hospital, if the infant receives care out of the
CHOP Care network, the infant’s primary care provider will be contacted for the anthropometric measurements including weight, length, and head circumference. If the infant remains within the CHOP Care network the infant’s anthropometric measurements are obtained from EPIC, the electronic medical record system at the Children’s Hospital of Philadelphia.

4.4 Infant Feeding Questionnaires

A set of standardized questionnaires are used to collect data on infant feeding practices, the first contact will be a questionnaire in hospital and all other contacts will take place in the hospital or at home (see Appendix for questionnaires). The infant feeding questionnaire collects information related to: breastfeeding and bottle-feeding practices, pumping, formula feeding practices, frequency and duration of feedings, and donor milk usage.

4.5 Demographic Questionnaire

Information regarding maternal and paternal education, occupation, ethnicity, race, and participation in government programs are collected at visit 1 via the demography questionnaire.

4.6 General Interview

The general interview questionnaire is used to obtain information regarding maternal age and marital status as well as paternal age, height and weight. This
questionnaire also collects data on the infant’s age, gender, age and gender of other siblings, and data on the persons living in the household with the infant.

4.7  Infant Medical History

Information on the infant’s medical history is obtained from a questionnaire which collects data on CHD diagnosis, gestational age, birth weight and length, any other diagnosis besides CHD, and surgical history of the infant.

4.8  Maternal Medication

A maternal medication questionnaire is obtained each visit to ascertain any medications the mother is currently taking or has taken in the past month and the indication for each medication.

4.9  Data Analysis and Statistics

Specific Aim 1: Describe breast feeding practices in the first six months of life in infants with CHD. To assess Aim 1, descriptive statistics (means, standard deviation, number, percent) were used to describe feeding practice variables, by month, from birth through 6 months of age.

Specific Aim 2A: Assess duration of feeding breastmilk/breastfeeding in infants with CHD who had no re-hospitalizations after original discharge from the hospital from birth to 6 months of age compared to those who had one or more re-hospitalizations after discharge. To assess Aim 2A, a t-test was used to assess for differences in
duration of feeding breastmilk/breastfeeding in months (dependent variable) by re-
hospitalization (independent variable).

Specific Aim 2B: Assess duration of exclusive breastmilk feeding/breastfeeding in
infants with CHD who had no re-hospitalizations after original discharge from the
hospital from birth to 6 months of age compared to those who had one or more re-
hospitalizations after discharge. To assess Aim 2B, a t-test was used to assess for
differences in duration of exclusive breastmilk feeding/breastfeeding in months
(dependent variable) by re-hospitalization status (independent variable).

Specific Aim 3: Assess duration of feeding breastmilk/breastfeeding in infants with
CHD who have received enteral tube feeding versus those who have not. To assess
Aim 3, a t-test was used to assess duration of breastmilk feeding/breastfeeding
(months, dependent variable) by enteral tube feeding status (ever received enteral tube
feedings; independent variable) from birth to 6 months of age.
Chapter 5

RESULTS

5.1 Parent and Infant Demographics

Parent and infant demographics for the 43 parent-infant dyads enrolled are summarized in Table A1. Thirty-three infants (76.7%) are White/Caucasian, six (14%) are Black/African American, one (2.3%) are Asian/Asian American, two (4.7%) are more than one race, and one (2.3%) mother reported infant’s race as ‘other’. Thirty-eight (92.7%) of subjects are Non-Hispanic or Latino infants 3 (7.3%) are Hispanic or Latino infants enrolled (7.3%)

Four (9.3%) of mothers reported finishing high school as their highest level of education and one (2.3%) mother reports trade school as her highest degree. The majority of mothers (n=24, 55.8%) reported having 1-4 years of college education and 13 mothers (30.2%) reported having a graduate education. Similarly, the majority of fathers (n=23, 53.4%) reported having 1-4 years of college, 11 fathers (25.5%) reported having graduate education, 6 fathers (13.9%) reported high school as their highest and two (4.6%) report trade school as their highest degree. Thirty mothers (71.4%) reported that they had an occupation other than being a mother while 39 fathers (90.6%) reported having an occupation other than being a father. The mean age for the mothers and fathers enrolled was 31±4.9 and 32.9±6.0 years old
respectively. Only 9 participants (21%) reported ever partaking in a federal nutrition education program, with 7 of the 9 (19%) currently participating.

5.2 Infant Medical History

The medical history for the 43 infants enrolled in the study are summarized in Table A2. The mean gestational age of the infants enrolled is 38.6±0.8 weeks, with a mean birth weight of 3.4±0.4 kg, and a mean birth length of 49.6±2.3 cm. The CHD diagnoses in high prevalence include: Hypoplastic left heart syndrome (HLHS; N=13, 30.2%), Transposition of the great arteries-left (TGA-L; N=6, 13.9%), Truncus arteriosus (TA; N=5, 11.6%), Tetralogy of Fallot (TOF; N=4, 9.3), Double outlet right ventricle (DORV; N=2, 4.6%), Transposition of the great arteries-right(TGA-D; N=2, 4.6%), Interrupted aortic arch (IAA; N=2, 4.6%), Double inlet left ventricle (DILV; N=2, 4.6%), Tubular hypoplasia of the aortic arch (THAA; N=2, 4.6%), Pulmonary atresia (PA; N=2, 4.6%).

5.3 Infant Feeding History at 2 Weeks

Infant feeding history at from birth to 2 weeks of age (feedings prior to study enrollment) is summarized in Table A3. Thirty-three (78.6%) of the infants were reported to have ever been breastfed directly at the breast, while 9 (21.4%) were reported to never have been directly breastfed. Twenty-five (75.8%) women reported that the Cardiac Intensive Care Unit (CICU) was the location that they first breastfed their infant. Prior to their infant’s surgery, 24 (55.8%) of women were able to
successfully breastfeed, and only 19 (44.2%) of women were able to successfully breastfeed after surgery. Twenty-nine (67.4%) women reported that they received help with breastfeeding, 20 (46.5%) reported that the nurse helped them, 23 (53.5%) reported receiving help from the lactation consultant, 4 (9.3%) women reported receiving help from their family members, and 1 (2.3%) woman reported receiving help from friends. When asked how helpful the breastfeeding help was that they received from the hospital staff, the mothers reported an average of 4.5±0.8 out of 5, with 1= “Not at all helpful” and 5= “Very helpful”. When asked how they felt about breastfeeding the first week, the mothers reported an average of 4.0±1.0 out of 5, with 1= “Disliked very much” and 5= “Liked very much”.

When asked what problems they experienced while breastfeeding, 10 (23.3%) mothers reported no problems. Fifteen (45.5%) mothers reported experiencing pain during the first two weeks of breastfeeding. A common problem reported was “My baby had trouble latching on” with 13 (30.2%) mothers reporting this issue. The second most common problem reported was “My baby wouldn’t wake up to nurse regularly enough” with 12 (27.9%) mothers reporting this issue. A majority (n=33, 76.7%) of mothers reported more than one issue with breast feeding.

Mother’s reported that it took an average of 3.2±0.9 days for their breastmilk to come in. Twelve women (28.6%) reported using donor milk to feed their infants during the first two weeks while 39 (90.1%) mothers report using a bottle to feed their infant. The average age of infants when they received their first bottle was 4.7±1.3 days. When asked about tube feeding, 36 (85.7%) mothers report that their infant was
tube fed. Ten infants (23.8%) were exclusively formula fed in the first two weeks with the average age of infant at first formula feeding being 7.2±4.4 days old. At the time of enrollment (when infants were two weeks of age), 40 (93%) of mothers reported that they were still pumping, with 37 (86%) reporting that they first were able to pump 0-6 hours after giving birth.

5.4 Specific Aim 1: Infant Feeding Through Six Months of Age

This study is on-going, and at present 39 infants have completed the 1-month visit, 36 infants have completed the 2-month visit, 34 infants have completed the 3-month visit, 31 infants have completed the 4-month visit, and 23 infants have completed the 6-month visit. Descriptive data on mode and type of feedings through six months of life are summarized in Table A4.

5.4.1 Month 1

At the 1-month, 4 mother-infant dyads (10.2%) were contacted while the infant was still hospitalized, while 35 (89.7%) were contacted at home. Of the four hospitalized infants, three (75%) were being fed ‘breastmilk fortified with powder formula’ and one (25%) was being fed ‘mix of breastmilk and formula’. Only one (25%) of these participants reported attempting to feed directly from the breast and two (50%) participants reported feeding breastmilk from a bottle, while one (25%) participant reported feeding exclusively formula. All four (100%) of the mothers with hospitalized infants reported that they were currently pumping, no participants (0%)
report using donor breastmilk, and all 4 mothers (100%) reported that their infant had received 100% of feedings via nasogastric tube in the past month.

Of the 35 subjects who were at home during the 1-month study visit, eighteen mothers (51.4%) were able to feed their infant at the breast successfully before they left the hospital, 34 (97.1%) reported feeding their infant any breastmilk, and zero mothers reported using donor breastmilk. Six (17.1%) of the 39 infants were readmitted to the hospital for an average of 6.0±7.0 nights. At the time of hospital discharge, 18 infants (51.4%) were receiving ‘breastmilk only’, 14 (40.0%) were receiving ‘breastmilk fortified with powder formula’, 1 (2.8%) was feeding ‘formula only’, and 2 (5.7%) were feeding ‘mix of breastmilk and formula’. The mode by which infants were fed varied; only one infant (2.8%) was solely breastfed, 10 (28.5%) infants were receiving both breast feedings and bottle feedings, 2 (5.7%) infants were receiving breast feedings and tube feedings, 10 (28.5%) infants were receiving bottle feeding and tube feeding, 3 (8.5%) infants were receiving tube feedings only, 4 (11.4%) infants were bottle feeding, breast feeding and tube feeding, and 6 (17.1%) of infants were bottle feeding only.

At 1 month, it was reported that 12 (34.2%) infants were receiving ‘breastmilk only’, the majority of infants (n=15, 42.8%) were receiving ‘breastmilk fortified with powdered formula’, 2 (5.7%) infants were receiving ‘formula only’, and 6 infants (17.1%) were being fed ‘mix of breastmilk and formula’.
5.4.2 Months 2, 3, 4, 6

The percentage of infants who were fed ‘any breastmilk’ declined steadily from 95% at month 1 to 75% at month 2 and 73.5%, 67.7%, and 52.2% at month 3, 4, and 6 respectively. The percentage of infants receiving ‘breastmilk only’ is also decreased over time with 30.8%, 32.4%, 32.4%, 29%, and 13% of infants exclusively receiving breastmilk at months 1, 2, 3, 4, and 6 respectively. Similarly, the number of infants receiving feedings at the breast also decreased throughout from 17 infants (43.6%) at month 1, to 4 infants (17.4%) at month 6. The number of infants being fed breastmilk in a bottle also decreased from 79.5% at month 1 to 58.8% at month 3 to 43.5% at month 6. ‘Formula only’ as the sole source of feeding increased over time with 2 infants (5.1%) receiving exclusively infant formula at month 1 to 11 infants (47.8%) at month 6. Also, the number of women still pumping breastmilk declined from 35 mothers (89.7%) at month 1 to 20 mothers (58.8%) at month 3 and 9 mothers (39.1%) by month 6. Similarly, the number of infants receiving feeding through a nasogastric tube declined as well from 24 infants (61.5%) at month 1 to 8 infants (23.5%) at month 3 and 8 infants (34.7%) at month 6. The number of infants that were re-hospitalized in the past month varied with 10 infants (27.7%) at month 1, 8 infants (22.2%) at month 2, 5 (14.7%) at month 3, 8 (25.8%) at month 4, and 12 infants (52.1%) at month 6. The number of nights spent in the hospital ranged from a mean of 6.0±7.0 nights at month 1 to mean of 18.6±19.6 nights at month 6.
5.5 Specific Aim 2

To test Aim 2A (assess duration of feeding breastmilk/breastfeeding in infants who had no re-hospitalization after original discharge from birth to 6 months of age compared to those who had one or more re-hospitalizations after discharge) a t-test was conducted with duration of feeding breastmilk/breastfeeding in months as the dependent variable and re-hospitalization as the independent variable. There was no significant difference (p=0.95) in duration of feeding breastmilk/breastfeeding in infants who were never re-hospitalized after discharge (mean±sd, 3.6±1.6 month) versus infants who were re-hospitalized one or more times after discharge (mean±sd, 3.6±1.6 months).

To test Aim 2B (assess duration of exclusive breastmilk feeding/breastfeeding in infants who had no re-hospitalization after original discharge from birth to 6 months of age compared to those who had one or more re-hospitalizations after discharge) a t-test was conducted with duration of exclusive breastmilk feeding/breastfeeding in months as the dependent variable and re-hospitalization as the independent variable. There was no significant difference (p=0.40) in duration of exclusive breastmilk feeding/breastfeeding infants who were never re-hospitalized after discharge (mean±sd, 1.75±1.98 months) versus those who were re-hospitalized one or more times after discharge (mean±sd, 1.05±1.69 months).
5.6  Specific Aim 3

To test Aim 3, (assess duration of breastmilk feeding/breastfeeding in infants with CHD who have received enteral tube feeding versus those who have not) a t-test was conducted using duration of feeding breastmilk/breastfeeding in months as the dependent variable and enteral tube feeding status (ever received enteral tube feedings) from birth to 6 months of age as the independent variable. There was no significant difference (p=0.68) in duration of breastmilk feeding/breastfeeding in infants who were fed with an NG tube (mean±sd, 3.71± 1.43 months) versus those who were never fed with an NG tube (mean±sd, 4.0±1.73 months).
Chapter 6

DISCUSSION

The overall aim of this study was to describe the feeding characteristics of infants with Congenital Heart Disease (CHD) as well as assess the effects re-hospitalization and nasogastric tube feeding has on breastmilk feeding/breastfeeding exclusivity and duration. Although these data are preliminary, our analysis found the following. The majority of infants in this study had complex heart defects such as hypoplastic left heart syndrome and transposition of the great arteries. Nearly a quarter of infants with CHD received formula within the first two weeks of life. At two weeks of age, the majority (78.6%) of infants had fed directly at the breast, an incidence just slightly less than the national average of 81.1%\textsuperscript{47}. We found that the number of infants with CHD who received any breastmilk steadily declined over the first 6 months from 95% at month 1 to 52.2% at month 6 which is similar in the general population (81.1% and 51.8% respectively)\textsuperscript{47}. Similarly, the number of infants being fed breastmilk exclusively declined from 32.4% at month 3 to 13% at month 6 compared to the general population which averages at 44.4% at month 3 and 22.3% at month 6\textsuperscript{47}. The vast majority of mothers in our study (90.4%) reported pumping breastmilk within 24 hours of delivery, an incidence higher than that reported in a similar population of mothers with infants with CHD (76%)\textsuperscript{45}. The number of times that mothers of infants...
with CHD pump breastmilk was similar as well\textsuperscript{45}. Mothers of infants with CHD in this study met or exceeded the average volume of breastmilk pumped per day (632mL/d) compared to an average from a similar population (500mL/d)\textsuperscript{45}.

We found no significant difference in duration of feeding breastmilk/breastfeeding for the first 6 months of life in infants who were re-hospitalized versus those who were not. The mean duration of feeding breastmilk/breastfeeding was 3.6 months, whether re-hospitalized once or more. We also found that re-hospitalization did not influence exclusive feeding of breastmilk/breastfeeding in the first 6 months of life. Infants who were only hospitalized once had a mean duration of feeding breastmilk/breastfeeding of 1.75 months (±1.98). Similarly, infants who were hospitalized more than once had a mean of feeding breastmilk/breastfeeding of 1.05 months (±1.69). Lastly, we found no significant difference between infants being fed via an enteral tube or not and the duration that they are fed breastmilk/breastfed. Infants who were never fed via an enteral tube had a mean of 4.0 months (±1.73) of receiving breastmilk while infants who were fed via an enteral tube had a mean of 3.71 months (±1.43) of receiving breastmilk.

A strength of our study is the longitudinal follow up and the collection of diet data 9 times over 12 months. This allows for the description of trends over time, rather than one data point in time. To our knowledge, our study is the first to observe
breastfed infants with CHD for an entire year and to record not only type and mode of feeding and breastmilk practices, but also re-hospitalization and growth of the infants.

A limitation of this study is the preliminary nature of the data. Many of the infants have not reached 6 months in age, therefore at this stage our data is underpowered to detect differences in duration and exclusivity of breast feeding by clinical outcomes. While these analyses found no significant difference breast feeding duration and exclusivity in clinical sub-groups, these analyses will be repeated with all subjects at the conclusion of the study.
Chapter 7

CONCLUSION

Infants with congenital heart disease (CHD) are known to have poor growth in the first two years of life\textsuperscript{7}, and feeding practices for infants with CHD can impact current and future health outcomes. Poor growth in infants with CHD is related to longer hospital stays and can negatively affect developmental outcomes\textsuperscript{7,11}. Infants with CHD have been reported to have many difficulties with feeding such as choking, dysfunction with swallowing, and short feeding time due to shortness of breath, all of which can lead to insufficient energy and nutrient intake\textsuperscript{13}. It has been shown that these infants are more likely to receive a bottle as the first mode of feeding rather than breastfeeding\textsuperscript{12}. In the past, it was thought that infants with CHD were not able to breastfeed and that they should be fed only formula from birth\textsuperscript{24}. This belief has since been refuted\textsuperscript{46}. Breastmilk is considered the gold standard of feeding for all infants, healthy or ill\textsuperscript{26}, and there is little data on the success and course of infants with CHD receiving breastmilk directly from the breast or in a bottle during the first six months of life.

In the present study, we sought to describe breastfeeding practices among infants with CHD. Research on this topic is limited, and our study is the first to our knowledge to explore the incidence, duration, and exclusivity of breastfeeding/feeding
breastmilk in the first year of life in infants with complex CHD. Though preliminary, our results suggest that infants with CHD are like their healthy peers in terms of feeding at the breast in the first two weeks of life. However, over time, these infants have lower incidences of exclusive breastmilk feeding at three and six months compared to the general population. Our preliminary results suggest that re-hospitalization did not impact duration and exclusivity of feeding breastmilk, however rates of breastmilk feeding declined at a faster rate in infants with CHD compared to the general population. At this time, the growth data is not ready for analysis, however we question whether the decline in incidence of breastmilk feeding could be related to growth issues, since it does not at this time appear to be related to re-hospitalization nor enteral tube feeding. Further analysis utilizing the full data set (0-12 months) is needed to better understand the feeding practices of infants with CHD during the first year of life.

The results of this study, when complete, have the potential to impact clinical practice. These data are important since in the United States, CHD occurs with an incidence of 8 per 1,000 births\(^2\) and is also the leading cause of infant mortality\(^3,4\). It is important to understand contemporary breastfeeding practices of infants with CHD to better inform practicing physicians, registered dietitians, lactation consultants, and parents, on the typical course of breastfeeding throughout the first year of life and factors that may influence exclusivity and duration.
REFERENCES


16. Fetal echocardiography / your unborn baby's heart. American Heart Association Web site. [http://www.heart.org/HEARTORG/Conditions/CongenitalHeartDefects/SymptomsDiagnosisofCongenitalHeartDefects/Fetal-Echocardiography-Your-Unborn-Babys-Heart_UCM_315640_Article.jsp#.V8h-VLxJ3R0](http://www.heart.org/HEARTORG/Conditions/CongenitalHeartDefects/SymptomsDiagnosisofCongenitalHeartDefects/Fetal-Echocardiography-Your-Unborn-Babys-Heart_UCM_315640_Article.jsp#.V8h-VLxJ3R0). Updated 2016.


Appendix A

TABLES

Table A1 - Demographic Characteristics of Infants and Parents (N=43)

<table>
<thead>
<tr>
<th>N (%)</th>
<th>Infant Ethnicity</th>
<th>Infant Race</th>
<th>Maternal Education</th>
<th>Paternal Education</th>
<th>Parental Age</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hispanic or Latino</td>
<td>3 (7.3)</td>
<td>White or Caucasian</td>
<td>33 (76.7)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not Hispanic or Latino</td>
<td>38 (92.7)</td>
<td>Black or African American</td>
<td>6 (14.0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Asian or Asian American</td>
<td>1 (2.3)</td>
<td>Asian or Asian American</td>
<td>1 (2.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Native Hawaiian or Pacific Islander</td>
<td>0 (0)</td>
<td>Native Hawaiian or Pacific Islander</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Two or More Races</td>
<td>2 (4.7)</td>
<td>Two or More Races</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>1 (2.3)</td>
<td>Other</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N (%)</td>
<td>4 (9.3)</td>
<td>1-4 y of trade school</td>
<td>1 (2.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1-4 y of college</td>
<td>25 (58.1)</td>
<td>1-4 y of college</td>
<td>25 (58.1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>More than 4 y of college</td>
<td>13 (30.2)</td>
<td>More than 4 y of college</td>
<td>13 (30.2)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12 y of high school</td>
<td>6 (13.9)</td>
<td>12 y of high school</td>
<td>6 (13.9)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1-4 y of trade school</td>
<td>2 (4.6)</td>
<td>1-4 y of trade school</td>
<td>2 (4.6)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1-4 y of college</td>
<td>23 (53.4)</td>
<td>1-4 y of college</td>
<td>23 (53.4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>More than 4 y of college</td>
<td>11 (25.5)</td>
<td>More than 4 y of college</td>
<td>11 (25.5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean±SD</td>
<td></td>
<td>Maternal Age, years</td>
<td>31.0±4.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Paternal Age, years</td>
<td>32.9±6.0</td>
<td></td>
</tr>
</tbody>
</table>

SD= Standard deviation, y=Years
NOTE: Data are preliminary, additional data are forthcoming.
Table A2- Infant Medical History at 2 Weeks (N=43)

<table>
<thead>
<tr>
<th>CHD Diagnosis</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HLHS</td>
<td>13 (30.2)</td>
</tr>
<tr>
<td>TGA-L</td>
<td>6 (13.9)</td>
</tr>
<tr>
<td>TA</td>
<td>5 (11.6)</td>
</tr>
<tr>
<td>TOF</td>
<td>4 (9.3)</td>
</tr>
<tr>
<td>DORV</td>
<td>2 (4.6)</td>
</tr>
<tr>
<td>TGA-D</td>
<td>2 (4.6)</td>
</tr>
<tr>
<td>IAA</td>
<td>2 (4.6)</td>
</tr>
<tr>
<td>DILV</td>
<td>2 (4.6)</td>
</tr>
<tr>
<td>THAA</td>
<td>2 (4.6)</td>
</tr>
<tr>
<td>PA</td>
<td>2 (4.6)</td>
</tr>
<tr>
<td>Single Ventricle</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>Pulmonary Vein Stenosis</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>TAPVR</td>
<td>1 (2.3)</td>
</tr>
</tbody>
</table>

**Infant Birth Characteristics**

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Mean±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Gestational Age, weeks</td>
<td>38.6±0.8</td>
</tr>
<tr>
<td>Mean Birth Weight, kg</td>
<td>3.4±0.4</td>
</tr>
<tr>
<td>Mean Birth Length, cm</td>
<td>49.6±2.3</td>
</tr>
</tbody>
</table>

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- Infant Feeding History from Birth to 2 Weeks (N=43)

<table>
<thead>
<tr>
<th></th>
<th>N (%) or Mean±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Breastfeeding Success</strong></td>
<td></td>
</tr>
<tr>
<td>Fed directly at the breast during the 1st 2 weeks of life</td>
<td>33 (78.6)</td>
</tr>
<tr>
<td>Never fed directly at the breast</td>
<td>9 (21.4)</td>
</tr>
<tr>
<td>First breastfed in the CICU</td>
<td>25 (75.8)</td>
</tr>
<tr>
<td>Successfully breastfed before surgery</td>
<td>24 (55.8)</td>
</tr>
<tr>
<td>Successfully breastfed after surgery</td>
<td>19 (44.2)</td>
</tr>
<tr>
<td>Able to hold their infant skin-to-skin during the 1st 2 weeks of life</td>
<td>28 (65.1)</td>
</tr>
<tr>
<td><strong>Breastfeeding Help</strong></td>
<td></td>
</tr>
<tr>
<td>Received help with breastfeeding</td>
<td>29 (67.4)</td>
</tr>
<tr>
<td>Received help from Nurse</td>
<td>20 (46.5)</td>
</tr>
<tr>
<td>Received help from Lactation Consultant</td>
<td>23 (53.5)</td>
</tr>
<tr>
<td>Received help from family members</td>
<td>4 (9.3)</td>
</tr>
<tr>
<td>Received help from friend(s)</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td><strong>Breastfeeding Problems</strong></td>
<td></td>
</tr>
<tr>
<td>Experienced pain while breastfeeding</td>
<td>15 (45.5)</td>
</tr>
<tr>
<td>No problems while breastfeeding</td>
<td>10 (23.3)</td>
</tr>
<tr>
<td>“My baby had trouble latching on”</td>
<td>13 (30.2)</td>
</tr>
<tr>
<td>“My baby wouldn’t wake up to nurse regularly enough”</td>
<td>12 (27.9)</td>
</tr>
<tr>
<td>“My baby was not interested in nursing”</td>
<td>7 (16.2)</td>
</tr>
<tr>
<td>“My baby had trouble sucking”</td>
<td>4 (9.3)</td>
</tr>
<tr>
<td>“My baby choked”</td>
<td>4 (9.3)</td>
</tr>
<tr>
<td><strong>Feeding Frequency and Mode</strong></td>
<td></td>
</tr>
<tr>
<td>Average time for breastmilk to come in, days</td>
<td>3.2±0.9</td>
</tr>
<tr>
<td>Used donor milk</td>
<td>12 (28.6)</td>
</tr>
<tr>
<td>Infant received tube feeding</td>
<td>36 (85.7)</td>
</tr>
<tr>
<td>Infant received infant formula</td>
<td>10 (23.8)</td>
</tr>
<tr>
<td>Average age of first formula feed, days</td>
<td>7.2±4.4</td>
</tr>
<tr>
<td>Ever botte fed infant</td>
<td>39 (90.1)</td>
</tr>
<tr>
<td>Average age received first bottle, days</td>
<td>4.7±1.3</td>
</tr>
<tr>
<td>Able to pump 0-6 hours after delivery</td>
<td>37 (86.0)</td>
</tr>
<tr>
<td>Mother still pumping breastmilk</td>
<td>40 (93.0)</td>
</tr>
</tbody>
</table>

SD= Standard deviation, CICU= Cardiac Intensive Care Unit
NOTE: Data are preliminary, additional data are forthcoming.
Table A4- Feeding Characteristics for the First 6 Months of Life, by Month

<table>
<thead>
<tr>
<th></th>
<th>1 month (N=39)</th>
<th>2 months (N=36)</th>
<th>3 months (N=34)</th>
<th>4 months (N=31)</th>
<th>6 months (N=23)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Feeding</strong></td>
<td>N (%) or Mean±SD</td>
<td>N (%) or Mean±SD</td>
<td>N (%) or Mean±SD</td>
<td>N (%) or Mean±SD</td>
<td>N (%) or Mean±SD</td>
</tr>
<tr>
<td>Fed any BM</td>
<td>37 (94.9)</td>
<td>26 (72.2)</td>
<td>26 (76.5)</td>
<td>21 (67.7)</td>
<td>12 (52.2)</td>
</tr>
<tr>
<td>Fed BM only</td>
<td>12 (30.8)</td>
<td>12 (33.3)</td>
<td>11 (32.4)</td>
<td>9 (29.0)</td>
<td>3 (13.0)</td>
</tr>
<tr>
<td>BM fortified with formula</td>
<td>18 (46.2)</td>
<td>7 (19.4)</td>
<td>4 (11.8)</td>
<td>4 (12.9)</td>
<td>4 (17.4)</td>
</tr>
<tr>
<td>Mix of BM and formula</td>
<td>7 (17.9)</td>
<td>8 (22.2)</td>
<td>10 (29.4)</td>
<td>8 (25.8)</td>
<td>5 (21.7)</td>
</tr>
<tr>
<td>Formula only</td>
<td>2 (5.1)</td>
<td>10 (27.8)</td>
<td>9 (26.5)</td>
<td>10 (32.3)</td>
<td>11 (47.8)</td>
</tr>
<tr>
<td><strong>Mode of Feeding</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any feeding at breast</td>
<td>17 (43.6)</td>
<td>16 (44.4)</td>
<td>13 (38.2)</td>
<td>8 (25.8)</td>
<td>4 (17.4)</td>
</tr>
<tr>
<td>Fed BM in bottle</td>
<td>35 (89.7)</td>
<td>21 (58.3)</td>
<td>22 (64.7)</td>
<td>16 (51.6)</td>
<td>10 (43.5)</td>
</tr>
<tr>
<td>NG tube feeding</td>
<td>24 (61.5)</td>
<td>10 (27.8)</td>
<td>8 (23.5)</td>
<td>7 (22.6)</td>
<td>8 (34.8)</td>
</tr>
<tr>
<td><strong>Factors that Impact Feeding</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother still pumping</td>
<td>35 (89.7)</td>
<td>24 (66.7)</td>
<td>20 (58.8)</td>
<td>15 (48.4)</td>
<td>9 (39.1)</td>
</tr>
<tr>
<td>Hospitalization in the past month</td>
<td>10 (25.6)</td>
<td>8 (22.2)</td>
<td>5 (14.7)</td>
<td>8 (25.8)</td>
<td>12 (52.2)</td>
</tr>
<tr>
<td>Average # of nights in hospital</td>
<td>6.0±7.0</td>
<td>6.4±3.1</td>
<td>4.4±3.2</td>
<td>9.3±6.6</td>
<td>18.6±19.6</td>
</tr>
</tbody>
</table>

SD= Standard Deviation, BM=breastmilk, NG=nasogastric
NOTE: Data are preliminary, additional data are forthcoming.
Appendix B

STUDY VISIT DOCUMENTS
A.1 Institutional Review Board Approval Letter

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.
A.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.

CHOP IRB#: «ID»
Effective Date: «ApprovalDate»
Expiration Date: «ExpirationDate»
**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.

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

CHOP IRB#: «ID»
Effective Date: «ApprovalDate»
Expiration Date: «ExpirationDate»
### Inclusion/Exclusion Criteria Form

**Inclusion Criteria:**

- Infant is ≥ 37 and ≤ 42 week gestation at birth
- Infant is a singleton
- Infant is appropriate for gestational age
- Infant has been diagnosed with congenital heart disease
- Infant has undergone or will undergo neonatal corrective or palliative surgery prior to discharge
- Mother is ≥ 18 years of age
- Mother is English speaking
- Mother intents to breastfeed

**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.)
A.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 breastfeed 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 ☐ I had a clogged milk duct
☐ My baby had trouble latching on ☐ My baby nursed too often
☐ I didn’t have enough milk ☐ My breasts were infected or abscessed
☐ My baby choked ☐ It took too long for my milk to come in
☐ My nipples were sore, cracked, or bleeding ☐ My breasts leaked too much
☐ My baby wouldn’t wake up to nurse regularly enough ☐ I had trouble getting the milk flow to start
☐ I had a yeast infection of the breast ☐ I had some other problem
☐ My baby got distracted ☐ My baby didn’t gain enough weight
☐ My baby was not interested in nursing ☐ My baby lost too much weight
☐ My baby got distracted ☐ 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? ____________
A.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  ☐ 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: Rachele 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 □ 20-29 minutes □ 40-49 minutes
    □ 10-19 minutes □ 30-39 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? ________________________________

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A.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
   - 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
   - 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 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? ____________________
Monthly Infant Feeding Questionnaire – First home contact

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC
Title: Breastfeeding in Infants with Congenital Heart Disease
Subject No. __________ Visiting Date: __/__/__

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 you, the mother, between breastfeeding or expressing milk? Please consider both day and nighttime 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? __________________________

__________________________________________________
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? ____________________________

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A.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
   - 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
   - 10-19 minutes
   - 20-29 minutes
   - 30-39 minutes
   - 40-49 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 tested 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
A.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) ____________________________
A.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 ♂ ♂

7. What is the birth order of the child currently enrolled in the study? __________

8. 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.)

<table>
<thead>
<tr>
<th>RELATION:</th>
<th>AGE:</th>
<th>SMOKER? (Yes / No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self</td>
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<tr>
<td>__________</td>
<td>__________</td>
<td>__________</td>
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</tbody>
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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: ________________________________
A.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: __________________

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A.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: __/__/__

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<th>Medications - Breastfeeding Mothers</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Are you taking any medications or have you taken any in the past month?</td>
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<td><em>If yes, please record below:</em></td>
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<tr>
<td>Medication Name:</td>
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<td>Reason:</td>
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<td>Circle one of options below:</td>
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<td>Prophylactic Use</td>
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<td>Treatment for ________________</td>
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<td>Treatment for ________________</td>
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<td>Reason:</td>
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