BREASTFEEDING INFANTS

WITH CONGENITAL HEART DISEASE

by

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ABSTRACT

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 [12]. 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.

Chapter 2

REVIEW OF THE LITERATURE

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[14].

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)[15]. 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)[16]. These procedures are commonly used to identify problems with the heart structure or incorrect blood flow.

2.1.1 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[15].

2.1.1.1 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[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[17].

2.1.1.2 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[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[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[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[14].

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[15].

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[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[14]. The left ventricle, ascending aorta, and mitral valves are all under developed 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[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[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[19].

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[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[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[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[22,23]. 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[2]. 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].

2.2 Feeding Infants with CHD Post Surgery

At times, breastfeeding has been misconstrued to mothers of infants with CHD as impossible or worthless[24,25]. The reality is that breastfeeding is the gold standard for feeding all infants, healthy or ill[26]. 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[24,25]. 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[24]. 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[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[28,29]. One study found that 50% of infants who underwent surgical intervention showed inadequate growth while 30% fell below the third percentile[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[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[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[34,35]. As such, it has been suggested that poor energy intake may be another factor contributing to poor growth in infants with CHD[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[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[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[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[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 fed[41]. 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 fed[42]. 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 placement[43].

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[26]. However, the most common feeding method for infants with CHD has been reported to be bottle-feeding[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[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[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[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[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[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[25]. Parents of infants with CHD reported being more intense and serious during feeding time compared to parents of healthy infants[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[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 ether 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[46].

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[39]. 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[24]. 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[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[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[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[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 much 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 asses 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%[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)[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[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%)[45]. The number of times that mothers of infants

with CHD pump breastmilk was similar as well[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)[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[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[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[13]. It has been shown that these infants are more likely to receive a bottle as the first mode of feeding rather than breastfeeding[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[24]. This belief has since been refuted[46]. Breastmilk is considered the gold standard of feeding for all infants, healthy or ill[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.

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Appendix A

TABLES

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

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

SD= Standard deviation, y=Years
NOTE: Data are preliminary, additional data are forthcoming.

Table A2- Infant Medical History at 2 Weeks (N=43)

CHD Diagnosis	**N (%)**
HLHS	13 (30.2)
TGA-L	6 (13.9)
TA	5 (11.6)
TOF	4 (9.3)
DORV	2 (4.6)
TGA-D	2 (4.6)
IAA	2 (4.6)
DILV	2 (4.6)
THAA	2 (4.6)
PA	2 (4.6)
Single Ventricle	1 (2.3)
Pulmonary Vein Stenosis	1 (2.3)
TAPVR	1 (2.3)
Infant Birth Characteristics	**Mean±SD**
Mean Gestational Age, weeks	38.6±0.8
Mean Birth Weight, kg	3.4±0.4
Mean Birth Length, cm	49.6±2.3

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)

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

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

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

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

UNIVERSITY OF DELAWARE
RESEARCH OFFICE

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

DATE: August 5, 2016

TO: Jillian Trabulsi, PhD
FROM: University of Delaware IRB

STUDY TITLE: [813477-2] Breastfeeding in Infants with Congenital Heart Disease

SUBMISSION TYPE: Amendment/Modification

ACTION: ACKNOWLEDGED
EFFECTIVE DATE: August 5, 2016

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

The following items are acknowledged in this submission:

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

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

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.

What are the study procedures?

The study involves the following procedures.

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

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

Visit/Contact Schedule

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

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

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

What are the risks of this study?

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

Are there any benefits to taking part in this study?

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

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

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

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

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

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

Can you stop your participation in the study early?

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

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

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

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

What choices do you have other than this study?

There are options for you other than this study including:

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

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

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

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

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

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

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

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

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

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

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

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

Additional Information

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

Financial Information

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

Will there be any additional costs?

There are no additional costs for participating in this study.

Will you be paid for taking part in this study?

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

Who is funding this research study?

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

What if you have questions about the study?

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

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

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

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

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

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

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

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

A.3 Inclusion/Exclusion Criteria Form

Inclusion/Exclusion Criteria

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

Inclusion Criteria:

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

Exclusion Criteria:

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

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 breast feed or try to breastfeed your baby for the very first time?

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

Where did you first breastfeed?

❒ SDU ❒ CICU ❒ Birth hospital ❒ Other_____

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

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

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

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

❒ Doctor ❒ Lactation Consultant ❒ Friend(s) ❒ Midwife
❒ Nurse ❒ Family Member(s) ❒ Other:_____

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

1 2 3 4 5

Infant Feeding History: Visit 1 at 2 weeks

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

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

1 2 3 4 5

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

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

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

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

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

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

If so, how old was your infant? _____ days

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

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

Infant Feeding History: Visit 1 at 2 weeks

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

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

   How many feedings per day? _____

   How many feedings from the breast? _____

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

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

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

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

   _____ Hours AND _____ Minutes

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

   If so, from whom:

   ❒ Nurse ❒ Lactation Consultant ❒ Other:_____

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

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

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

   How many feedings per day from the bottle? _____

Monthly Infant Feeding Questionnaire – In hospital

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

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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? _____

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

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

b. Calorie concentration _____

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

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

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

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

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

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

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

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

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

When was this?

❒ Week 1 ❒ Week 2 ❒ Week 3 ❒ Week 4

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

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

How many feedings per day? _____

How many feedings from the breast? _____

Monthly Infant Feeding Questionnaire – First home contact

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

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

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

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

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

_____ Hours AND _____ Minutes

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

If so, from whom:

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

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

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

Location: Home Hospital Other: _____

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

How many feedings per day from the bottle? _____

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

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

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

If yes, how many times per day? _____

Daily milk production_____

Which pump are you using? _____

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

Monthly Infant Feeding Questionnaire – First home contact

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

---

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

16. Are you currently using formula? Yes No

If yes, name of formula? _____

If yes, how much per feeding? _____

If yes, how often per day? _____

If yes, how many oz per day? -_____

Concentration_____

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

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

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

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

Amount of powder _____ scoops

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

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

If *Yes*, what? _____

How much? _____

How often? _____

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

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

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

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

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 <u>currently</u> feeding?**

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

   How many feedings per day? _____

   How many feedings from the breast? _____

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

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

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

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

   _____ Hours AND _____ Minutes

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

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

   Other: _____

Monthly Infant Feeding Questionnaire – all other home contacts

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

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5. **Has your infant been test weighed to determine volume of breastmilk consumed?** Yes No
   If so: Date(s):_____Volume:_____

6. **Are you currently feeding your infant a bottle?** Yes No
   How many feedings per day from the bottle? _____

7. **Are you currently feeding expressed breast milk in a bottle?** Yes No
   If yes, is it fortified? _____concentration_____
   If yes, how much per feeding? _____
   If yes, how often per day? _____
   If yes, how many oz per day? _____

8. **Are you currently pumping?** Yes No
   If so, how many times per day? _____
   Daily milk production_____
   Which pump are you using? _____
   If you are no longer pumping, when and why did you stop? _____
   _____

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

10. **Are you currently using formula?** Yes No
    If yes, name of formula? _____
    If yes, how much per feeding? _____
    If yes, how often per day? _____
    If yes, how many oz per day? _____
    Concentration_____

Monthly Infant Feeding Questionnaire – all other home contacts

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

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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 <u>YOUR</u> (Mother) ethnic category?

- ❑ Hispanic or Latino
- ❑ Not Hispanic or Latino

What is <u>YOUR</u> (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 <u>YOUR CHILD'S FATHER'S</u> ethnic category?

- ❑ Hispanic or Latino
- ❑ Not Hispanic or Latino

What is <u>YOUR CHILD'S FATHER'S</u> 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 <u>YOUR CHILD'S</u> 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 ♀ ♂

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

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

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

General Interview Form: Visit 1

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

_____	_____	_____
_____	_____	_____
_____	_____	_____

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

    Your (Mom's) weight: _____ lbs.

QUESTIONS ABOUT THE CHILD'S FATHER

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

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

      _____
    - ❑ Email: _____

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: __/__/__

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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: _____

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: __/__/__

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