GROWTH, BREASTFEEDING, AND TOTAL ENERGY EXPENDITURE IN INFANTS WITH CONGENITAL HEART DISEASE

by

Chelsea L. Hollowell

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

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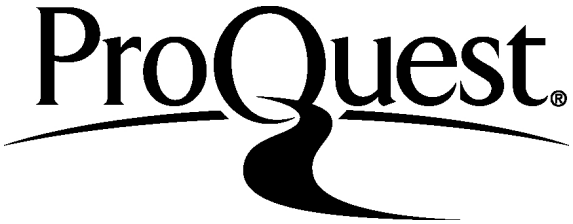

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Approved: _____

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

Approved: _____

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

Approved: _____

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

Approved: _____

James G. Richards, Ph.D.
Vice Provost for Graduate and Professional Education

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ABSTRACT

Background: Approximately 30,000 to 35,000 infants per year are born with a congenital heart defect (CHD); the defects range from mild to more severe in complexity and often affect other aspects of infant health. Infants with congenital heart disease (CHD) often fail to maintain a normal growth pattern when compared to healthy infants of a similar age. Poor growth in infancy can affect many aspects of health such as neuro-developmental attributes, immune function, wound healing, and subsequent growth in childhood. The growth failure observed in some infants with CHD is hypothesized to be due to a combination of inadequate energy intake and increased energy expenditure. There is a gap in the literature, however, regarding contemporary infants with CHD, feeding practices, and total energy expenditure in this population.

Objective: This study has two primary aims. The first aim is to design a study to examine factors that affect breastfeeding exclusivity and duration in infants with CHD post-surgical intervention (Aim 1). The second aim is to determine if total energy expenditure (TEE) of infants with CHD post-surgical intervention, differs from healthy (control) infants (Aim 2).

Hypothesis: We hypothesize that the challenges of breastfeeding infants with CHD will be similar, in part, to those reported by mothers of healthy infants, with a greater

emphasis on concerns related to growth of the infant. It is hypothesized that TEE in infants with CHD, post-surgical intervention, would not be increased compared to healthy controls

Design: To address Aim 1, a longitudinal study of breastfeeding in infants with CHD was designed. This study will recruit 75 infant-mother dyads from the Children's Hospital of Philadelphia's Cardiac Intensive Care Unit. Infant-mother dyads will be followed for 12 months and questionnaires regarding breastfeeding, growth, and other aspects of infant feeding will be administered 9 times over a 12-month period. This study is currently under review with the Institutional Review Board at the Children's Hospital of Philadelphia. To address Aim 2, 26 infants with CHD were recruited at birth from the Children's Hospital of Philadelphia Cardiac Intensive Care Unit and 24 healthy control infants were recruited from the surrounding area. Total energy expenditure was assessed at 3 months and 12 months in healthy control infants and infants with CHD after surgical intervention..

Results:

The longitudinal study of breastfeeding in infants with CHD is currently under review by the Institutional Review Board at the Children's Hospital of Philadelphia. The study of TEE in infants with CHD after surgical intervention found that TEE for CHD infants was not significantly different from healthy infants at 3 months and 12 months; TEE in CHD infants was 36.4 kcal/day higher (95% CI: -46.3, 119.2; $p = 0.37$) and 31.7 kcal/day higher, (95% CI: -71.5, 134.8; $p = 0.53$) at 3- and 12- months, respectively, compared to healthy infants.

Conclusion: There was no significant difference found in measured TEE between infants with CHD who had undergone surgical intervention within the first 30 days of life and healthy age-matched controls, at 3 months or 12 months of age. As such, the growth failure observed in these infants is likely due to decreased energy intake rather than increased energy expenditure. A focus on understanding and optimizing nutrient intake in this population is needed to support age appropriate growth in infants with CHD.

Chapter 1

INTRODUCTION

Congenital heart disease occurs during fetal development and includes a myriad of structural and physiologic variations such as: conotruncal defects, pulmonary venous anomalies, left-sided defects, septal defects, right-sided defects and others [1]. The etiology of CHD is not well understood however environmental and genetic factors are thought to play key roles in the development [1]. Environmental factors could include maternal illness, intake of teratogenic materials and possibly parental age [1]. Genetic factors can include numerical chromosomal abnormalities, the microscopic deletion on certain chromosomes and single gene mutations, which can also affect other organs besides the heart [1]. The majority of infants diagnosed with moderate to severe forms of CHD undergo palliative or corrective surgery, this ranges from catheter procedures to surgical repairs [1]. Infants with CHD often fail to maintain a normal growth pattern in comparison to their healthy counterparts [1-6], suggesting malnutrition, which can also affect cognitive and motor development. The reason(s) for poor growth observed in these infants is unclear, but is thought to be due to a combination of insufficient energy intake and increased energy expenditure. A better understanding of nutrient intake and energy expenditure during this time period is needed to inform practices that support age appropriate growth.

Chapter 2

REVIEW OF THE LITERATURE

2.1 Congenital Heart Disease

Amidst all birth defects, the leading cause of infant mortality is congenital heart disease [1]. Eight in every 1,000 live births results in a congenital heart defect totaling approximately 30,000-35,000 occurrences per year, in the United States [2,4-6]. Common types of congenital heart defects include ventricular septal defect (VSD), tetralogy of Fallot (TOF), and pulmonary valve stenosis (PVS) [1,7-9].

In a properly functioning heart, the blood flows as follows: oxygen poor blood from the body enters the right atrium of the heart and empties through the tricuspid valve into the right ventricle. From the right ventricle, blood is pumped through the pulmonary valve into the pulmonary artery and into the lungs. The lungs oxygenate the blood and return oxygenated blood to the heart via the pulmonary veins to the left atrium. From the left atrium, the blood flows through the mitral valve into the left ventricle of the heart which pumps the oxygen rich blood through the aortic valve into the aorta and out to the body [7].

Prior to surgical repair, the normal flow of blood through the heart in an infant with CHD is disrupted [7]. Acyanotic defects include left to right shunts and obstructive physiologies. Left to right shunts shuffle-oxygenated blood from the left heart to the

right heart or the aorta through a hole between the two sides. Obstructive physiologies are caused by a blockage of the blood flow, which results in a pressure gradient. This gradient can lead to hypertrophy or heart failure. Cyanotic anomalies result in un-oxygenated blood shunting from the right heart to the left heart. These defects are developed during the first eight weeks of fetal development and cause the infant to turn blue after birth, called cyanosis. Consequences of these defects vary from an asymptomatic heart murmur to circulatory collapse [1].

2.1.1 Surgical Procedures

Over the past decade, there has been a decrease in morbidity and mortality rates in infants with CHD due to improved corrective and palliative surgeries [5]. These improvements have decreased the mortality rate in this population by 2.8%, in recent years, with 85% percent of children born with CHD now surviving into adulthood and leading normal, active lives [7,10-12].

Infants with CHD are either treated via catheter or surgical procedures. Catheter procedures are the preferred method for simple defects, such as atrial septal defect, and can repair holes within the heart walls or enlarge a narrow valve. For more complex defects or multiple defects, surgery can close holes in the heart, repair heart valves and repair problems with the location of blood vessels [1]. Heart transplants do occur, but these are rare and only in very extreme cases with multiple defects [7].

2.1.2 Single Ventricle and Biventricular Physiologies

Infants with CHD are often classified as having a single ventricle or biventricular physiology. A single ventricle defect is characterized by one functioning ventricle compared to the normal heart, which is biventricular [3]. Single ventricle defects are rare, occurring in 5 of every 100,000 live births [3]. Surgeries for these defects are usually palliative, meaning the problem is not completely corrected but rather alleviated. Surgeries often occur in multiple steps and aim to restore oxygenation by connecting the blood without oxygen to the pulmonary arteries. Following the procedures, these infants still have single ventricle physiologies [3]. This ventricle, which supplies both systemic and pulmonary blood flow, has a significant volume load [13]. Biventricular physiologies have two functioning ventricles.

2.2 Growth of Infants with CHD

With improvement in survival rates, the focus of caring for infants with CHD now includes managing growth after surgery [12]. After surviving surgery, adequate weight gain is a common stressor for parents of infants with CHD [13]. Malnutrition and growth failure are common comorbidities for infants with CHD with almost half of infants younger than 2 years old being stunted [10,12-16]. These less than optimal growth rates can continue through adolescence for some infants [2,4,5]. Growth can be a strong indicator of nutritional status and a predictor of future health and wellbeing [17]. A study of 89 children with CHD found that 65% and 41% of infants were below the 5th percentile for weight and height, respectively [18]. Attempting to provide feedings with

adequate calories to support nutritional status and age appropriate growth is a goal for infants with CHD.

Energy imbalance, and energy intake less than total energy requirements, is a major contributing factor to poor growth in children with CHD. It can influence the metabolic response to injury and also the outcome after corrective cardiac surgery [16]. Insufficient energy intake with the CHD population could be due to a number of factors including a hypermetabolic state, inadequate caloric intake, swallowing dysfunction, malabsorption, gastroesophageal reflux, immaturity of the gastrointestinal tract, genetic factors or decreased accrual of fat mass [13,14]. Growth failure, while likely multifactorial in nature, is thought to be related to inadequate energy intake and/or increased energy expenditure [15,19]. This imbalance affects not only growth but also cognitive and motor development, wound healing and immune function [13,16]. The energy required for growth during infancy includes energy put towards developing new tissue and the energy to sustain these tissues [16]. Growth occurs when energy intake exceeds total energy expenditure (TEE) [19]. A study by Irving et al, suggests that low weight for age z scores found in this population are due to low fat mass, and not fat free mass, further supporting the notion of insufficient energy intake. Infants with cyanotic versus acyanotic physiologies have been reported to grow differently. Infants with cyanotic defects often demonstrate decreases in both weight and height compared to healthy infants. Infants with acyanotic defects and left to right shunts have been found to have less weight gain but age appropriate linear growth during infancy [16].

2.3 Feeding in Infants with CHD

Infants with CHD have also been reported to have more difficulties feeding compared to healthy infants. Feedings are frequently postponed due to clinical status, medical tests, and/or gastrointestinal issues, all of which may contribute to insufficient energy intake.

According to the American Academy of Pediatrics, breastfeeding is the preferred form of feeding for all infants, healthy, ill and preterm infants [20]. Breastfeeding confers numerous positive effects including nutritional, immunological, and emotional benefits [4,21]. These benefits are even more profound for premature infants and infants with special medical needs. For infants with CHD, human milk is better absorbed than formula and provides growth factor that support intestinal mucosa maturity [13]. For years it had been thought that breastfeeding was more difficult than bottle-feeding for infants with CHD, but this has recently been refuted [2,22]. In fact, a recent study found that breast-feeding maybe be less physiological work for the infant with CHD compared to bottle-feeding [22]. Another study of 45 infant mother pairs found that infants with CHD who were breastfed had shorter hospital stays compared to their bottle-feeding counterparts [21]. Furthermore, infants who were bottle-fed fell significantly further off the normal growth curve than their breastfeeding counterparts [21]. Discouraging breastfeeding on the basis that weight gain is poor is not appropriate for all infants with CHD; breastfeeding appears to be equal to or less than the physiologic work of bottle-feeding, and breast milk may be fortified with additional nutrients for infants for whom insufficient intake volume is an issue. Given the

benefits of breastfeeding, it is surprising that few studies have examined breastfeeding in infants with CHD post-surgery.

2.3.1 Frequency of breastfeeding in infants with CHD

Healthy People 2020 set a target for 81.9% of all infants to be breastfed at least once; as a point of reference, data from 2006 show that 74% of infants achieved breastfeeding at least once. In a study performed in Norway, researchers found mothers of infants with moderate/severe CHD and CHD with comorbidities were at an increased risk to wean their infants from breast-milk feedings earlier than mothers of healthy infants [23]. The prevalence of breastfeeding in infants with CHD, post surgical intervention in the US is currently unknown, but most likely is lower in comparison with the healthy infant population [4]. Mothers of infants with CHD must overcome barriers specific to this population, which mothers of healthy infants may not experience. These obstacles can affect initiation, duration and exclusivity of breastfeeding for mothers of infants with CHD.

2.3.2 Obstacles to breastfeeding infants with CHD

There is a paucity of data on the normal duration for breastfeeding an infant with CHD. Parental exhaustion in mothers is a possible barrier to breastfeeding in infants with CHD. Mothers have reported feeling their baby was constantly feeding, with feedings sometimes lasting up to 2 hours [5,24]. Infants with CHD have been described as difficult to feed as they will often take a small volume each feed and

become dyspnoeic during sucking [5,13,25]. Other barriers include lack of privacy in the hospital and medical treatments that affect feeding. Vomiting can also be an issue for infants with CHD, specifically those being tube fed, as they often do not signal when they are satiated [5,15,24]. Vomiting can lead to less weight gain and, for mothers, a sense that the feeding was wasted [5]. Both the severity and the longevity of these feeding difficulties can have significant long-term effects on both the infant and the family as a whole [25]. Infants with single ventricle physiologies are prone to these feeding difficulties and growth failure in particular. These problems can be life-long issues [24].

With respect to breastfeeding, one study reported that mothers of infants with CHD had received negative feedback on breastfeeding their infant from health care providers. Mothers were told that breastfeeding was more work for their infant than bottle-feeding [4]. In a study of 7 infants with CHD, researchers used pulse oximetry to measure oxygen saturation rates during both breast and bottle-feeding [22]. Oxygen saturation measures the amount of oxygen carried by the infant's red blood cells. Commonly lower in infants with CHD, low blood oxygen concentrations cause shortness of breath and a lack of oxygen supplied to cells and tissues for normal function [26]. The study found that oxygen saturation was actually higher during breastfeeding compared to bottle-feeding and was less variable; and while nursing, none of the infants with CHD completely desaturated, whereas 4 of the infants with CHD did desaturate completely during bottle-feeding [22].

2.3.3 Initiation, Duration & Exclusivity of Breastfeeding

Breastfeeding initiation usually occurs in the nursery when infants are stable and are able to show oro-motor cues [6]. However, infants with CHD often exhibit a delay in feeding cues and may not signal when they are hungry or satiated [12,17,20,24]. Infants with cyanotic heart defects have been shown to have significant delays in the time of initiation and the time until maximum nipple and gavage feeds [6,13]. Feeding issues in infants with CHD include difficulty suckling, prolonged stays in the intensive care unit, tube feeds and breathlessness [17]. Also, the length of time infants with CHD require respiratory support has been shown to affect the age at which maximum bottle and nipple feeding occurred [6]; resulting in delayed feedings for infants who were on support longer.

Pre- and post-operative fasting restrictions can also be an obstacle to initiation and duration of breastfeeding [2]. Most infants can resume breastfeeding 2.5 to 3.5 days post-surgery, but that is not always the case and some infants require a longer time [4]. With the necessary support and education, mothers of infants with CHD can successfully breastfeed their infants. Teaching mothers to adjust their breastfeeding plans to fit the special needs of an infant with CHD, which could include adding supplemental calories and sometimes foregoing feedings at the breast in order to pump for the infant, can create a more successful breastfeeding experience [2].

Even with the best intention to breastfeed, obstacles do occur. One study found that 83% of mothers whose infants were born with CHD had intended to breastfeed their infant, however only 68% of mothers were able to achieve this [24]. This study also

found a significant association between breastfeeding at discharge and continuing to breastfeed at 6 months; more than half of the infants breastfeeding at discharge had achieved full breastfeeds and there was a significant association between breastfeeding at discharge and breastfeeding at 6 months post discharge [24].

2.4 Energy Expenditure in Infants with CHD

The energy expenditure of infants with CHD has often been a topic of research given growth issues observed in this population. Studies regarding total energy expenditure (TEE) and resting energy expenditure (REE) in infants with CHD have yielded conflicting results [10,16], possibly due to the many factors that affect energy expenditure such as age, type and severity of cardiac defect, and surgical status (pre- or post-surgical intervention); further these studies are often limited by small sample sizes.

TEE is composed of three parts: basal metabolic rate, thermic energy of food and energy expenditure of activity [19,27]. Basal metabolic rate (BMR) is the energy utilized by the body during absolute rest; this energy is used for the maintenance of activities of basic life such as heart function, breathing and basic cellular operation [16]. It is measured in a supine position, after a night's sleep and 10-14 hour fast. Resting energy expenditure (REE) or resting metabolic rate (RMR) is similar to BMR, however it is measured in the supine position, after a person has been lying still for 20-30 minutes, with variable post-absorptive states [27]. Thermic effect of food includes the energy expended to digest, absorb and store food. Energy expenditure of activity

includes both activities of daily life considered non-exercise activity thermogenesis and exercise activity thermogenesis [27]. The difference between REE and TEE reflects the energy cost of physical activity [10].

REE is typically measured using open circuit indirect calorimetry and TEE may be measured using the doubly labeled water method. Both of these methods gather data on oxygen consumption and carbon dioxide production in order to calculate energy expenditure. The doubly labeled water method is a stable isotope technique used to measure TEE in free-living subjects. The method requires dosing the infant with water enriched with the stable isotopes oxygen-18 and deuterium (^2H). The isotopes are eliminated from the body in normal metabolic processes; oxygen -18 is eliminated via CO_2 and H_2O and deuterium is eliminated via H^2O. The difference in the elimination rates of these two isotopes is used to determine CO_2 production which in turn is used to calculate TEE [10].

Interestingly, TEE in infants with CHD has not been widely studied, especially in a contemporary population, post-surgical intervention.

2.4.1 Body Composition Prior to Surgical Intervention

Prior to surgery, infants with VSD have been found to be smaller in weight and length compared to healthy infant controls. Additionally these infants gained significantly less weight since birth compared to healthy counterparts. Fat mass in infants with VSD and other left to right shunt defects was found to be lower than that of healthy controls [10,15,19,28]. Fat mass accretion relates directly to energy intake while

fat free mass tends to be positively and significantly correlated to REE and TEE [14,29]. The mean percentage of body fat in infants with CHD pre-surgical correction was found to be 10.5% while normal body fat is 25% [28]. Infants who were experiencing congestive heart failure (CHF) had even lower fat masses [19]. Total body water (TBW) and fat free mass were found to be significantly smaller in infants with VSD in one study [10]. In another, on infants with left to right shunts, TBW was significantly higher than that of healthy infant controls. This could be explained by lower fat mass, increased hydration of the fat free mass or a combination of the two [15].

2.4.2 Energy Expenditure Prior to Surgical Intervention or No Intervention

Two studies of REE in infants with CHD and no surgical intervention, have found no significant difference in expenditure between infants with CHD and healthy control infants [10,15]. With respect to TEE, four studies have shown that TEE prior to surgical correction was elevated in infants with VSD and left to right shunts compared to healthy infants, with the highest TEE in infants with CHF [10,15,19,30]. The TEE of infants with VSD in the study by Ackerman et al was 40% higher than the TEE of the healthy infant controls [10]. In a study by van der Kuip, infants with CHD had significantly higher TEE than healthy controls [15]. Farrell et al found a significant difference in TEE between infants with CHD, infants with CHF and healthy controls with CHF having the highest and healthy controls the lowest [19]. Leitch et al performed a study published in 1998 on 10 infants with CHD and compared the TEE results to healthy controls at two separate time points, 2 weeks and 3 months. At the 2-week

time point, TEE was not significantly different in infants with CHD compared to healthy controls. At the 3-month time point, TEE was significantly increased in infants with CHD compared to healthy controls [30]. The growth retardation observed in this population of infants is likely due to elevated energy demands prior to surgery.

2.4.3 Energy Expenditure Post-Surgical Intervention

Leitch and colleagues reexamined energy expenditure in 7 infants from their previous study in 1998 [29]. At 5 years of age, approximately 2.6 years after surgical repair, there were no significant differences in TEE compared to healthy infants.

2.4.4 Energy Expenditure Pre- and Post-Surgical Intervention

Reports of TEE in infants with CHD post-surgical correction have been conflicting. Two studies have measured TEE prior to and after surgical intervention. In agreement with the four studies on TEE in infants with CHD prior to surgical intervention, a study by Barton et al measured TEE in 8 infants with CHD prior to surgical intervention and found TEE was significantly greater in infants with CHD. They repeated the study in 4 of the infants post surgical intervention and found no consistent pattern in TEE [28]. A study by Mitchell et al, measured TEE in 18 infants with CHD prior to surgery and again in 17 post-surgical intervention compared to healthy age-matched controls. Their results prior to surgical intervention at the group level showed no significant difference in TEE between healthy infants and those with CHD. When assessed at the individual level, energy expenditure was 20% above normal values in 5 of the 18 infants. When measured post-surgical intervention,

energy expenditure fell below preoperative levels and significantly below normal levels [31]. These three post surgical intervention studies show conflicting results in a non-contemporary cohort [28,29,31].

Chapter 3

SPECIFIC AIMS

3.1 Statement of the Problem

Growth failure in infants with CHD is common, and can affect other aspects of health such as motor and cognitive development and immune function. A factor that likely contributes to poor growth is insufficient energy intake. While breastfeeding is accepted as a suitable feeding method for infants with CHD, there is lack of information about the factors that affect breastfeeding in these infants.

The growth failure observed in some infants with CHD may also be related to energy expenditure. Total energy expenditure prior to surgery is elevated for infants with CHD; however studies on TEE in infants who have undergone surgical intervention are conflicting. A better understanding of both breastfeeding obstacles and TEE in infants with CHD is needed to guide nutrition interventions and promote age appropriate growth within this population.

3.2 Specific Aims

This thesis has two primary aims:

Aim 1: Design a study to examine factors that affect breastfeeding initiation, exclusivity and duration in infants with CHD post-surgical intervention

Aim 2: Determine if total energy expenditure (TEE) of infants with CHD post-surgical intervention differs from healthy (control) infants in the first year of life

Additionally we will:

- Determine which of the predictive equations used to calculate TEE in infants with CHD post-surgical intervention is most accurate. (Aim 2a)

Chapter 4

METHODS

4.1 Aim 1: Breastfeeding the Infant with Congenital Heart Disease

4.1.1 Description of Participants

Seventy-five infant-mother dyads will be recruited from the Cardiac Intensive Care Unit at the Children's Hospital of Philadelphia and will be followed for 12 months. The following inclusion and exclusion criteria must be met for participation in the study.

Inclusion criteria:

Subjects must meet all of the following criteria to be enrolled in the study.

At birth:

1. Infants must be a healthy, term (≥37 and ≤42 week gestation at birth), singleton, appropriate for gestational age infant.

At the time of enrollment:

1. Infants must have been diagnosed with preoperative form of congenital heart disease
2. Infants must have undergone corrective surgery with single or biventricular post surgery physiologies

3. Infants must be receiving breast milk feedings.

Mother must be:

1. ≥ 18 years of age.

Exclusion criteria:

Presence of any of the following criteria will exclude the subject from enrollment in the study.

1. Infant must not have any other known anomalies

4.1.2 Description of Variables

Information regarding infant feeding practices will be recorded using a standardized questionnaire (see accompanying submission documents). The questionnaires collect information related to: breastfeeding practices, obstacles to breastfeeding, pumping and feeding breast milk, frequency of feedings, bottle feeding and formula feeding practices. Weight and length at hospital discharge will also be recorded. The infant's weight and length throughout the first year of life will be obtained from the outpatient medical record.

4.1.3 Procedures

Women and their infants will be recruited at the Children's Hospital of Philadelphia's Cardiac Intensive Care Unit. Initial interviews using a standard script (**see Appendix**) will be conducted in person to determine initial interest and preliminary eligibility. If

a parent is interested in participating, the first study visit will be scheduled. At the first study visit, the informed consent process will occur and mothers/parents will be given the opportunity to ask any questions they may have about the study. If the IRB - approved ICF is signed by the mother, the mother-infant pair will be assigned a subject number. All subjects who sign an informed consent will be listed on the Subject Master List. Each mother-infant dyad will be screened for all inclusion and exclusion criteria. If a mother- infant dyad complies with all of the inclusion and exclusion criteria, the pair will be enrolled into the study. If the mother-infant dyad does not comply with one or more of the inclusion or exclusion criteria the pair will be defined as a screening failure, and the reason for screening failure will be recorded on the Subject Master List.

Study Visit Procedures

The informed consent process will be completed at the beginning of the first study visit. After the informed consent is signed, study visit 1 procedures include:

- Inclusion, exclusion screening
- Collect contact information
- Complete the following questionnaires:
    - Parent and Infant Demography
    - General Interview
    - Infant Medical History
    - Infant Feeding History

- Infant Anthropometry
- Monthly Infant Feeding
- Medications

Subsequent study visits (2-9):

If infant is still in the hospital, will be in person visit and forms for in hospital (designated ‘a’) will be used. If infant is at home, will be a telephone contact and forms for home (designated ‘b’) will be used.

- Complete the following questionnaires:
  - Infant Anthropometry
  - Monthly Infants Feeding (A or B)
  - Medications

4.1.4 Statistical Analysis

All data will be inspected for normality after collection. Parametric statistics will be used for normally distributed data and non-parametric models will be used for data that is not normally distributed. Numeric data will be summarized and reported as means ± standard deviations. Categorical data will be reported as numbers and percentages.

4.2 Aim 2: Total Energy Expenditure in Infants with Congenital Heart Disease

4.2.1 Description of Participants

Fifty infants were recruited from either the Children's Hospital of Philadelphia's (CHOP) Cardiac Intensive Care Unit (CICU) or it's well-child care clinics across the city of Philadelphia and surrounding suburbs. The study sample contains 26 infants with CHD and 24 healthy control infants.

Inclusion criteria:

All subjects met the following criteria for enrollment in the study.

1. ≥ 36 weeks gestational age
2. ≥ 2500 g at birth

For infants with CHD, the following criterion was also satisfied for enrollment:

1. Corrective surgery was performed within the first 30 days of life

Exclusion criteria:

Meeting any of the following criteria excluded subjects from participation.

1. Congenital anomalies other than CHD
2. Facial, chromosomal, neurologic or complex gastrointestinal anomalies

4.2.2 Description of Variables

Information regarding anthropometric measurements including weight, length and head circumference were collected using standard techniques. Body composition,

a two-compartment model comprised of fat mass and fat free mass, was determined using Total Body Electrical Conductivity instrument (TOBEC). Total energy expenditure was measured using the doubly labeled water (DLW) technique. Formulas used to calculate total energy requirements included: The Academy of Nutrition and Dietetics Pediatric Nutrition Care Manual (120 kcal/kg), Pediatric Nutrition in Chronic Diseases and Development (120-170 kcal/kg), the 1989 Recommended Dietary Allowance for 0-6 months and 6-12 months and the Dietary Reference Intakes Estimated Energy requirements (EER) for 0-6 months and 7-12 months.

4.3 Procedures

Study Visit Procedures

The informed consent process was completed at the beginning of the first study visit.

4.3.1 Description of Instruments

Instruments used include the TOBEC for determination of body composition, a digital scale to measure weight, an infantometer for recumbent length measurement, a non-elastic tape measure for head circumference, and doubly labeled water for TEE.

4.3.2 Statistical Analysis

Descriptive statistics were used to describe the subject population and cardiac defects. Data were analyzed across the three sub-populations in the study: a healthy

infant control group, infants with CHD and biventricular post-surgery physiology, and infants with CHD and single ventricle post-surgery physiology. Multiple linear regression models were used to examine associations between TEE and health status (healthy versus CHD); separate regression models were run for TEE at 3-months of age and 12-months of age and fat free mass was a covariate in all models. To evaluate the accuracy of equations used to estimate energy intake at the group level, the difference between calculated TEE and measured TEE as well as the ratio of calculated TEE relative to measured TEE was determined. To evaluate the accuracy of equations at the group level, calculated TEE was regressed onto measured TEE and the root mean square error, Wald-statistic P value and squared multiple coefficient of determination were examined.

Chapter 5

RESULTS

5.1 Aim 1: Breastfeeding the Infant with Congenital Heart Disease

The protocol, informed consent, and data collection forms have been submitted to the Internal Review Board (IRB) at the Children's Hospital of Philadelphia for review. Upon IRB approval, recruitment will be initiated and the electronic study database will be developed.

5.2 Aim 2: Total Energy Expenditure in Infants with Congenital Heart Disease

5.2.1 Subject Characteristics

A total of 50 subjects had complete data and TEE measurements at 3 months, 12 months or both time points. At 3 months, there were 12 healthy infants and 15 infants with CHD. At 12 months, there were 12 healthy infants and 11 infants with CHD. Of the 26 total infants with CHD at both time points, 8 had single ventricle physiologies and 18 had biventricular physiologies. The three most common physiologies were hypoplastic left heart syndrome (HLHS), D-transposition of the great arteries (D-TGA) and tetralogy of fallot (TOF) **(Table 1)**.

The majority of subjects in both the healthy cohort and the infants with CHD were male. There were no significant differences in the proportion of males in the single ventricle versus biventricular physiology CHD groups nor between the healthy infants and all infants with CHD (Chi-square p=0.59 and p=0.62 respectively) **(Table**

2). There were no significant differences in race or ethnicity between the single versus biventricular physiology CHD groups nor between all infants with CHD versus healthy infants (Chi-square for race: p=0.19 and p=0.13; Chi-square for ethnicity: p=0.22 and p=0.27) **(Table 2)**. There were no significant differences between the healthy infants and the infants with CHD regarding birth weight or birth weight z scores. (t-test, p=0.2813 and p=0.4021 respectively) **(Table 2)**.

5.2.2 Body Composition and TEE

At 3 months of age, there were no significant differences in age, weight, weight for age z score, length for age z score, head circumference z score, weight for length z score, fat free mass, total body water or TEE between healthy infants and all infants with CHD. There was a significant difference in the dilution space ratio, which was slightly higher in the infants with CHD (p=0.05), but still within the normal range **(Table 3).** At 12 months of age, there were no statistically significant differences among the groups, however, weight for length z score and length for age z score approached significance (p=0.07 and p= 0.08 respectively), with infants with single ventricle and biventricular physiologies having lower weight for length z-scores compared to healthy infants.

The results from multiple linear regression analysis showed a non-significant association between health status (healthy versus CHD) and TEE, with adjustment for fat free mass, at both the 3 and 12-month time points. At 3 months, TEE for infants with CHD was 36.4 kcal/day higher when compared to healthy infants, (95% CI: -46.3, 119.2 kcal/day; p=0.37), although this difference did not reach significance. At 12 months, the average TEE for infants with CHD was 31.7 kcal/day higher when

compared to healthy infants (95% CI: -71.5, 134.8; p=0.53), again this did not reach significance.

5.2.3 Accuracy of formulas for calculating TEE

To determine which of the commonly used equations for estimating total energy requirements in infants with CHD was most appropriate for this population, summary statistics and a linear regression analysis were performed (**Table 4**). For group level performance, the smallest difference between calculated total energy requirements and measured TEE was the DRI equation [32]. For individual performance, the equation that resulted in the highest R^2 and lowest root mean square error was from the 1989 RDA [33]. **Figure 1** shows the relationship between calculated total energy requirements and measured TEE.

Chapter 6

DISCUSSION

The first aim of this thesis was to examine factors that affect breastfeeding initiation, exclusivity and duration in infants with CHD post-surgical intervention. Breastfeeding is universally acknowledged as the best source of nutrition for ill, preterm and healthy infants [20,21]. Despite this information, mothers of infants with CHD are more likely to use bottle-feeding as the first method of feeding their baby more often than mothers of healthy infants [17].

Previous studies on breastfeeding infants with CHD have reported that mothers often receive mixed information on whether or not their child is capable of breastfeeding from health care professionals [2]. Other concerns include frequent vomiting, caring for NG tubes, anxiety and pressure regarding weight gain and lengthy feed times [5]. Another common point of stress for parents feeding an infant with CHD is their lack of feeding cues signaling when they are satiated [5]. This can often lead to the infant vomiting and the mother feeling the feeding was wasted, increasing concern over adequate weight gain. However with support, a high percentage of mothers may be able to breastfeed their infants with CHD. One study reported that after implementation of a lactation support program, 85.3% of mothers whose infants had CHD were breastfeeding at 3 months and 64.7% were breastfeeding at 5 months. This

data shows that lactation support can positively influence breastfeeding rates in infants with CHD.

Another aspect of infant feeding that may be affected by CHD status, is age at weaning from breast-feeding. A study performed in Norway by Tandberg et al, collected information regarding feeding practices in 196 infants with CHD. They compared this data to a healthy cohort who completed the same questionnaire. The results showed that mothers of infants with moderate/severe CHD and CHD with comorbidities were at increased risk of weaning their infant earlier than mothers of healthy infants. At 6 months of age, 74% of infants with moderate/severe CHD were still receiving some form of breast milk compared to 84% of healthy infants.

We designed a study to further evaluate breastfeeding initiation, exclusivity and duration rates in a contemporary cohort of infants with CHD post-surgical intervention. The results of our study will provide detailed information on breastfeeding infants with CHD and factors that can be addressed to improve breastfeeding in this population.

The second aim of this thesis was to determine if total energy expenditure (TEE) of infants with CHD post-surgical intervention differs from healthy (control) infants in the first year of life. We found TEE, after adjustment for FFM, did not differ significantly between healthy infants and infants with CHD at 3 months and 12 months of age.

When comparing the results of our study to the literature, it is important to consider the populations studied (type of defects, whether surgical correction has

occurred, and the age of the infant). Previous studies by Ackerman et al, van der Kuip et al, Farrell et al and Leitch et al (1998) analyzed TEE in infants with CHD who had not received surgical intervention. Ackerman et al studied 8 infants with VSD aged 3-5 months old and compared their TEE measurements to 10 healthy controls. They found TEE was 40% higher in infants with CHD compared to healthy controls. Van der Kuip et al studied 11 infants with CHD compared to historical data of healthy infants. They also reported the infants with CHD had increased energy expenditure. Farrell et al studied 17 infants with VSD, 10 with congestive heart failure (CHF), compared to 13 healthy controls aged 3-5 months old. TEE was significantly different among all three groups with the lowest in healthy infants and the greatest in infants being treated for CHF. Leitch et al studied 10 infants with cyanotic congenital heart disease (CCHD) at two separate time points; 2 weeks and 3 months and compared results to 12 controls. They reported a slightly higher TEE for CCHD infants at 2 weeks, but not statistically significant. At 3 months, TEE was reported to be significantly increased.

Studies reporting TEE in infants with CHD who have undergone surgical intervention include Barton et al, Mitchell et al, and Leitch et al. Barton et al studied 8 infants prior to surgical intervention with severe CHD and found mean TEE was significantly greater than healthy infants. However, after reexamining 4 of the infants with CHD, post surgical procedure, no consistent pattern of energy expenditure was observed. Energy expenditure was dramatically decreased in one infant and slightly lower in another two while the fourth infant's energy expenditure was increased.

Mitchell et al performed a similar study in 18 infants with CHD 4-33 months in age. Prior to surgical intervention, TEE was not significantly different from normal values when assessed at a group level, however, when assessed individually expenditure was 20% above normal values in 5 of the 18 infants. In 17 infants reexamined immediately after surgical intervention, energy expenditure levels fell sharply below preoperative levels and significantly below normal levels. Finally, Leitch et al (2000) measured TEE in CHD after surgical intervention when they were 5 years of age. This study found no difference in TEE in infants with CHD compared to age matched healthy controls (Leitch 2000). Taken together, the results of these studies of TEE post surgical intervention show no consistent pattern.

The present study added to current literature by studying a sample size comparable to or larger than previous literature and by studying TEE in a more modern population with more advanced surgical intervention techniques. The study of TEE in infants with CHD did have limitations. The sample size was small, yet it was similar to or larger than the majority of the literature to date. The majority of the infants in our study had severe defects, thus the results may not apply to infants with more mild defects. Nor would the results be generalizable to infants without surgical intervention. In addition, energy intake was not measured during the study.

In summary, in our study of infants with CHD and complex diagnoses and surgical intervention, TEE of these infants was similar to healthy age-matched infants. The results of this study and those of others suggest that inadequate energy intake has the larger role in the poor growth observed in this population of infants following

surgical intervention. As such, energy intake should be considered one of the clinical and research priorities for prevention and treatment of poor growth in infants with CHD.

TABLES

Table 1: Pre- and Post-Operative Diagnoses and Physiology of Cohort

Preoperative Diagnosis	Postoperative Physiology Classification	
	Single Ventricle (n=8)	Biventricular (n=18)
	n (%)	*n (%)*
Hypoplastic left heart syndrome	4 (50)	0
Valvular pulmonary atresia	2 (25)	0
Double inlet left ventricle	1 (13)	0
L-Transposition of great arteries	1 (13)	0
D-transposition of great arteries	0	4 (22)
Tetralogy of fallot	0	4 (22)
Interrupted aortic arch	0	3 (17)
Coarctation of the aorta	0	2 (11)
Total anomalous pulmonary venous return	0	1 (6)
Truncus arteriosus	0	1 (6)
Double outlet right ventricle	0	1 (6)
Valvular septal defect	0	1 (6)
Aorto-Pulmonary Window	0	1 (6)

Table 2: Characteristics of Infant with Congenital Heart disease and Healthy Controls

	Healthy Infants	**Infants with Congenital Heart Disease (CHD)**		
		All CHD	**Single Ventricle**	**Biventricular**
	(n=24)	(n=26)	(n=8)	(n=18)
Gender	*n (%)*	*n (%)*	*n (%)*	*n (%)*
Male	17 (71)	20 (77)	7 (88)	13 (72)
Race				
African American	2 (8)	1 (4)	0 (0)	0 (0)
Caucasian	20 (84)	24 (92)	6 (74)	18 (100)
Other	2 (8)	1 (4)	1 (13)	0 (0)
Not reported	0 (0)	0 (0)	1 (13)	0 (0)
Ethnicity				
Latin/Hispanic	1 (4)	4 (15)	3 (38)	1 (5)
Non-Latin/Hispanic	20 (84)	19 (73)	4 (50)	15 (83)
Not Reported	2 (8)	0 (0)	0 (0)	2 (12)
Anthropometry	*mean (sd)*	*mean (sd)*	*mean (sd)*	*mean (sd)*
Birth weight, g	3514 (481)	3359 (529)	3186 (576)	3436 (505)
Birth weight, z-score	0.28 (0.90)	0.03 (1.18)	-0.37 (1.31)	0.21 (1.12)

No significant difference between healthy (control) infants versus all infants with CHD (t-test) nor among healthy (control) infants, CHD infants with single ventricle post-surgery physiology, CHD infants with biventricular post-surgery physiology for any of the above variables (ANOVA).

Table 3: Growth, Body Composition, and Total Energy Expenditure in Infants with Congenital Heart Disease and Healthy Controls

	Healthy Infants	Infants with Congenital Heart Disease		
		All CHD	Single Ventricle	Biventricular
	n=12	n=15	n=2	n=13
3 Months	*mean (sd)*	*mean (sd)*	*mean (sd)*	*mean (sd)*
Age at visit, days	92.8 (8.4)	94.1 (12.4)	102.5 (16.3)	92.8 (11.9)
Weight, kg	6.15 (0.69)	5.87 (0.94)	6.00 (2.03)	5.85 (0.83)
Weight for Age, z-score	-0.2 (1.0)	-0.62 (1.26)	1.02 (2.45)	-0.56 (1.15)
Length for Age, z-score	0.01 (1.0)	-0.08 (1.07)	-0.49 (0.96)	-0.02 (1.11)
Head Circumference for Age, z-score	0.4 (1.4)	0.25 (1.06)	-0.25 (1.45)	0.33 (1.04)
Weight for Length, z-score	-0 .34 (1.03)	-0 .75 (1.00)	-0.97(2.50)	-0.72(0.80)
Fat-free mass, kg	4.5 (0.5)	4.54 (0.65)	5.41 (0.0)	4.47 (0.63)
Total body water, kg	3.8 (0.4)	3.71 (0.70)	3.58 (0.91)	3.73 (0.71)
Dilution space ratio, N2/N18	1.025 (0.006)[§]	1.035 (0.016)[§]	1.025 (0.031)	1.036 (0.015)
Total energy expenditure, kg/d	403 (60	439 (138)	399 (100)	445 (148)

Table 3: Growth, Body Composition, and Total Energy Expenditure in Infants with Congenital Heart Disease and Healthy Controls (continued)

12 Months	n=12 *mean (sd)*	n=11 *mean (sd)*	n=6 *mean (sd)*	n=5 *mean (sd)*
Age at visit, days	366 (5.1)	373 (24.9)	375 (33.9)	370 (9.96)
Weight, kg	9.71 (0.81)	9.15 (1.18)	9.46 (1.45)	8.78 (0.71)
Weight for Age, z-score	0.21 (0.79)[§]	-0.72 (1.40)[§]	-0.65 (1.80)	-0.80 (0.90)
Length for Age, z-score	-0.07 (0.83) [§]	-1.10 (1.67) [§]	-1.53 (2.13)	-0.59 (0.84)
Head Circumference for Age, z-score	0.37 (0.82)	-0.22 (1.1)	0.19 (1.08)	-0.71 (0.90)
Weight for Length, z-score	0.02 (0.61)	0.07 (1.17)	0.26 (1.51)	-0.16 (0.33)
Fat-free mass, kg	6.78 (0.33)	6.92 (0.79)	7.01 (0.91)	6.74 (0.55)
Total body water, kg	5.56 (0.31)	5.70 (0.82)	5.77 (0.85)	5.59 (0.86)
Dilution space ratio, N2/N18	1.031 (0.017)	1.033 (0.011)	1.032 (0.010)	1.034 (0.012)
Total energy expenditure, kg/d	706 (91)	767 (124)	707 (86)	838 (133)

[§] Significant difference ($p<0.05$) between healthy (control) infants versus all infants with CHD for dilution space ratio at 3 months (t-test); No significant difference among healthy (control) infants, CHD infants with single ventricle post-surgery physiology, CHD infants with biventricular post-surgery physiology for any of the above variables (ANOVA).

Table 4: Accuracy of formulas for calculating total energy requirement for infants with CHD

			Indexes of model fit		
	Difference: Calculated TER— Measured TEE	Ratio: Calculated TER/ Measured TEE	R^2	*RMSE*	*p-value*
	kcal/d	%			
Formulas specific for children with CHD					
Academy of Nutrition and Dietetics Pediatric Nutrition Care Manual	293 ± 155	159 ± 36	0.58	139.3	<0.0001
Pediatric Nutrition in Chronic Diseases and Development	475 ± 183	192 ± 43	0.58	139.3	<0.0001
Formulas for healthy children					
2002 Dietary Reference Intake (DRI)[1]	79 ± 166	124 ± 35	0.38	169	0.008
1989 Recommended Dietary Allowance (RDA)[1]	272 ± 116	155 ± 29	0.62	108	<0.001

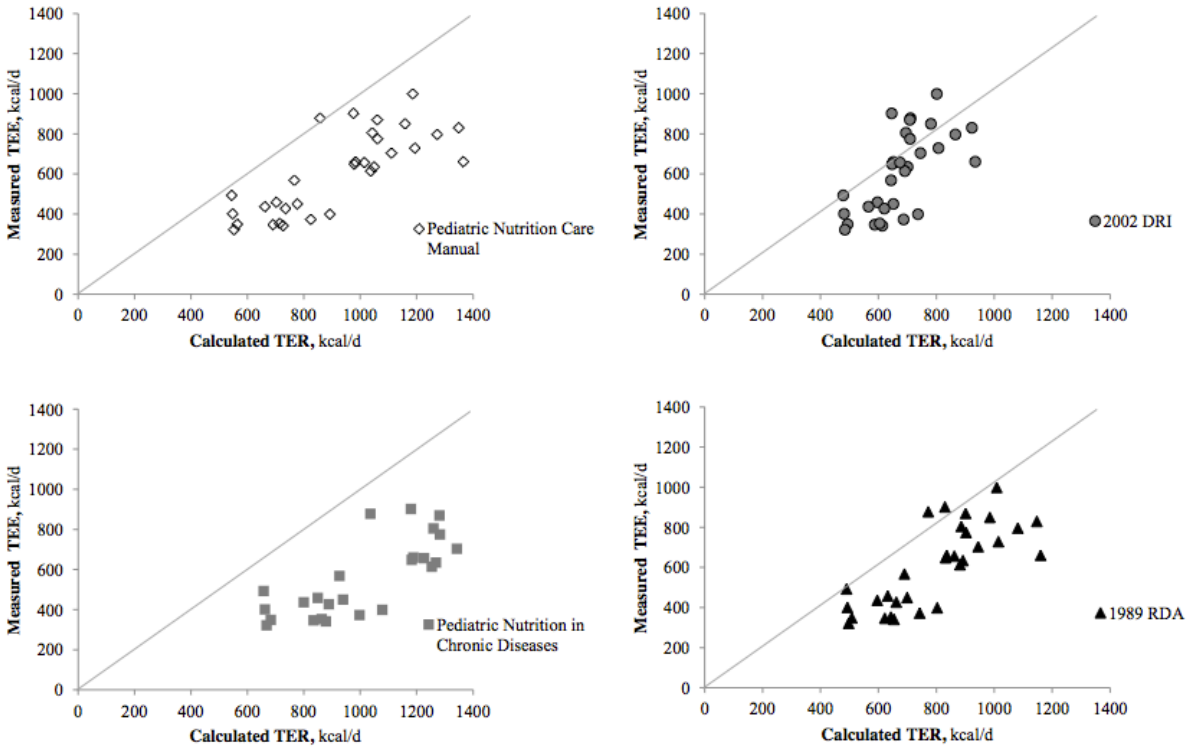
[1]These formulas differ in the first year of life according to infant age. Total energy requirements were first calculated using age of the infant and the corresponding formula for that age, and then the average for both time points (3-months and 12-months) was computed.

Table 5: Formulas for Calculating Energy Requirements for Healthy Infants and for Infants with Congenital Heart Disease

Reference	Formula	
Formulas for healthy children		
2002 Dietary Reference Intake (DRI)	0-3 months: 7-12 months:	(89 x wt [kg]-100) + 175 kcal (89 x wt [kg]-100) + 22 kcal
1989 Recommended Dietary Allowance (RDA)	0-6 months 6-12 months	108 kcal 98 kcal/kg
Formulas for children with CHD		
Academy of Nutrition and Dietetics Pediatric Nutrition Care Manual		120 kcal/kg
Pediatric Nutrition in Chronic Diseases and Development		120-170 kcal/kg

FIGURES

Figure 1: Relationship between calculated energy requirements and measured TEE.



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Appendix A

INFORMED CONSENT

The Children's Hospital *of* Philadelphia®

Informed Consent Form and HIPAA Authorization

Study Title:	Breastfeeding the Infant with Congenital Heart Disease	
Version Date:	August, 20, 2014	
Principal Investigator:	Rachelle Lessen, MS, RD, IBCLC, LDN	Telephone: 215-590-1089
Co-Investigator:	Jillian Trabulsi, PhD, RD	Telephone: 302-831-4991
Study Team member:	Chelsea Hollowell, BS (graduate student) Samantha Elliott, BS (graduate student)	
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 may 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	Routine Interview	Monthly Infant Feeding Questionnaire,	30 minutes

of birth +180 days		Maternal Medications	
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, 365 days of age	Final Interview	Monthly Infant Feeding Questionnaire, Maternal Medications Growth Data (Weight, length, head circumference) from your child's first year of life will be obtained from your primary care provider	30 minutes

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

Appendix B

STUDY FLOW CHART

Study Procedures	*Visit 1	**Contact 2	**Contact 3	**Contact 4	**Contact 5	**Contact 6	**Contact 7	**Contact 8	**Contact 9
	Week 1-2 or prior to hospital d/c	Date of birth + 30 days	Date of birth + 60 days	Date of birth + 90 days	Date of birth + 120 days	Date of birth + 180 days	Date of birth + 240 days	Date of birth + 300 days	Date of birth + 365 days
Informed consent	X								
Inclusion criteria	X								
Exclusion criteria	X								
General Interview Form	X								
Demography	X								
Infant Medical History	X								
Infant Feeding History	X								
Monthly Infant Feeding Questionnaires		X	X	X	X	X	X	X	X
Maternal Medications	X	X	X	X	X	X	X	X	X

* Enrollment
** If infant still in hospital will be in person visit and forms for in hospital will be used. If infant at home, will be a telephone contact and forms for home will be used.

Appendix C

QUESTIONNAIRES

Inclusion/Exclusion Criteria

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:__/__/__**

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 preoperative form of 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

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?**_____

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:__/__/__**

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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		

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:_____

Demography: 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:__/__/__

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

Demography: 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:__/__/__

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

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

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

What is YOUR (Mother) ethnic category?

- ❑ Hispanic or Latino
- ❑ Not Hispanic or Latino

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

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

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

- ❑ Hispanic or Latino
- ❑ Not Hispanic or Latino

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

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

What is YOUR CHILD'S ethnic category?

- ❑ Hispanic or Latino
- ❑ Not Hispanic or Latino

Demography: Visit 1

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC, Jillian Trabulsi, PhD RD
Co-investigators: Chelsea Hollowell, Samantha Elliott
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*) _____

Infant Medical History- Visit 1

Principal Investigator: Rachelle Lessen, MS, RD, IBCLC; Jillian Trabulsi, PhD RD
Co-investigator: Chelsea Hollowell
Title: Breastfeeding in infants with Congenital Heart Disease

Subject No. ___ ___ ___ ___ ___

Date of Visit: ____ /_____ /_____

1. **What was your infant's preoperative 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:_____

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:__/__/__**

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, Jillian Trabulsi, PhD RD
Co-investigators: Chelsea Hollowell, Samantha Elliott
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 breast 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 babylost too much weight
- ❒ I had no problems

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

If so, how old was your infant? _____ days

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

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

Infant Feeding History: Visit 1 at 2 weeks

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

---

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

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

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

Name of formula(s) _____

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

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

How old was baby when donor milk was started?

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

How many days did baby receive donor milk?

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

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

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

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

8. Was your baby ever tube fed? Yes No

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

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

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

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

Maternal Medications

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:__/__/__**

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:			

Monthly Infant Feeding Questionnaire – In hospital

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:__/__/__**

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 human milk: Skip to question # 10

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. **If mixed 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

4. **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

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

   If so, from whom:

   ❒ Nurse ❒ Lactation Consultant ❒ Other:_____

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

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

7. **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, Jillian Trabulsi, PhD RD
Co-investigators: Chelsea Hollowell, Samantha Elliott
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ **Visit Date:__/__/__**

---

8. 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?_____

9. 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?_____

_____

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

11. 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 _____

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

What percentage of feedings are via NG?_____

Monthly Infant Feeding Questionnaire – First home contact

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:__/__/__**

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

   a. **When was this?**

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

Monthly Infant Feeding Questionnaire – First home contact

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:__/__/__**

❒ 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 human milk: Skip to question # 16

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. **If mixed 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

10. **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

11. **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 – First home contact

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:__/__/__**

---

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

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

Location: Home Hospital Other:_____

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

How many feedings per day from the bottle? _____

14. 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?_____

15. 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? _____

---

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

17. 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 – First home contact

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:__/__/__**

---

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

a. 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?_____

Monthly Infant Feeding Questionnaire – all other home contacts

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:__/__/__**

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 human milk: Skip to question # 12

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. **If mixed 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

4. **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

5. **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, Jillian Trabulsi, PhD RD
Co-investigators: Chelsea Hollowell, Samantha Elliott
Title: Breastfeeding in infants with Congenital Heart Disease
Subject No._ _ _ _ _ **Visit Date:__/__/__**

---

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

If so: Date(s):_____Volume:_____

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

How many feedings per day from the bottle? _____

8. 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? _____

9. 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? _____

_____

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

11. 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_____