THE COURSE OF BREASTFEEDING AND DURATION OF FEEDING HUMAN MILK IN INFANTS WITH CONGENITAL HEART DISEASE

by

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ABSTRACT

Background: Although mothers of children with congenital heart disease are able to breastfeed successfully, the research on this population is limited and the effect of breastfeeding challenges and social support on human milk duration is unknown. Research aims/questions: This study aimed to describe the course of breastfeeding in infants with CHD from birth to 12 months of age, with a focus on breastfeeding characteristics (e.g., early lactation experiences, breastfeeding challenges, sources of breastfeeding support) and their relationship to the exclusivity and duration of feeding human milk. Methods: This study was a prospective, observational study conducted at The Children's Hospital of Philadelphia between 2015-2018. Participants were followed throughout the infant's first year of life, with 9 total contacts. Questionnaires were administered to mothers at each visit to obtain information on feeding type, sources of support, and challenges faced during breastfeeding. Results: 75 mother-infant dyads were enrolled. 93% of mothers reported having challenges, the most common (38%) being the infant having trouble latching. The majority of support was received within the first 0.5 months of the infant's life from lactation consultants (72%) and nurses (62%). The mean duration of 'any human milk' and 'human milk only' was 6.4 months and 3.19 months, respectively. Duration of 'human milk only' was related to mothers reporting infants having trouble sucking (p=0.03) and not having enough milk (p=0.04). Human milk durations were not related to receiving support. Conclusion: Mothers of infants with congenital heart disease were able to successfully provide their infants with human milk, despite commonly facing breastfeeding challenges and rehospitalizations

Chapter 1

INTRODUCTION

Congenital heart disease (CHD) is the leading type of birth defect in the United States, affecting almost 1% of births each year (Center for Disease Control and Prevention [CDC], 2019). The term CHD encompasses a number of conditions that affect the heart, including the walls, valves, arteries and veins of the heart (National Institute of Health [NIH], 2020). This, as a result, affects the circulation of blood in the heart and the rest of the body. The severity of different forms of CHD varies; and some forms of CHD may require one or more surgical interventions early in life followed by life-long medical attention (CDC, 2019).

Infants with CHD commonly have feeding difficulties such as vomiting (Hartman & Medoff-Cooper, 2012), trouble sucking and breathlessness (Clemente et al., 2001), often leading to insufficient energy intake (Hubschman, 2013). In combination with increased nutritional needs from surgical interventions and an increased metabolic rate prior to surgical intervention (Forchielli et al., 1994; Trabulsi et al. 2015), infants with CHD are at a higher risk for malnutrition (Forchielli et al., 1994; Medoff-Cooper & Ravishankar 2013) and failure to thrive (Tsintoni et at., 2019).

Breastfeeding is the gold standard for infant nutrition (American Academy of Pediatrics [AAP], 2012; Walker, 2010), and it has been shown that infants with CHD

who are breastfed experience less respiratory stress compared to bottle feeding (Marino et al., 1995). However, mothers of infants with CHD face additional stressors and barriers to breastfeeding, making it more challenging for them to meet breastfeeding recommendations (Lambert & Watters, 1998; Barbas & Kelleher, 2004). Therefore, it is important to examine the feeding practices, support received and challenges that mothers with infants with CHD face in order to help mothers meet recommendations and implement strategies to increase mothers' success.

The purpose of this study is to describe the course of breastfeeding in infants with CHD from birth to 12 months of age, including feeding patterns, support received and challenges faced.

Chapter 2

REVIEW OF THE LITERATURE

2.1 Breastfeeding as the Gold Standard

Breastfeeding is considered the gold standard for infant nutrition (AAP, 2012; Walker 2010). Not only has breastfeeding been associated with decreased incidence of a wide array of adverse health outcomes including childhood overweight, obesity, diabetes, reduced malocclusion, and necrotizing enterocolitis (AAP, 2021; Grummer-Strawn & Rollins, 2015), but infants who are exclusively breastfed for the first six months of life have lower infant mortality rates worldwide (Grummer-Strawn & Rollins, 2015). More specifically, breastfed infants have a 14-fold decrease in risk of mortality compared to those who are never breastfed (Sankar et al., 2015). Because of the well documented benefits of breastfeeding, the American Academy of Pediatrics (AAP), World Health Organization (WHO) and American College of Obstetricians and Gynecologists (ACOG) recommend exclusive breastfeeding for the first 6 months of life, with continued breastfeeding until at least one year along with the balanced introduction of solid foods (NIH, 2017). Early on, breastfeeding provides anti-inflammatory and immune-boosting benefits, exclusively breastfed infants are less likely to develop infections than those who are formula-fed (Cacho & Lawrence, 2017). Furthermore, the composition of breastmilk is dynamic and can change to meet the specific nutritional needs of the infant at any point in time. For example, preterm infant breastmilk is higher than term infant breastmilk in epidermal growth factor, phagocytes and secretory immunoglobulin A, which corresponds to increased needs of

premature infants (Cacho & Lawrence 2017). The various components of breastmilk are thought to each have a unique role in supporting the health of an infant at each stage of growth and development. Whether an infant is born full-term, pre-term, with a chronic disease, or with increased nutritional needs, breastmilk is the best form of nutrition for an infant to receive (Walker, 2010). There are relatively few contraindications to breastfeeding and a limited number of medical conditions in infants (e.g. galactosemia) or certain conditions in mothers (e.g. human T cell lymphotropic virus, untreated brucellosis, active untreated tuberculosis or active herpes) where breastmilk is not recommended (AAP, 2021). Despite breastmilk being recognized as the preferred method of feeding for infants, most infants in the US are not exclusively breastfeeding and do not continue to receive breastmilk as long as recommended (Office of the Surgeon General et al., 2011).

2.2 Breastfeeding Rates of Healthy Infants in the United States

Results from the National Immunization Survey conducted by the Centers for Disease Control and Prevention show that in the Unites States, approximately 80% of infants receive at least some breastmilk at birth; however, breastfeeding rates decrease to approximately 60% by 6 months of age. Only about 25% of breastfed infants receive breastmilk exclusively for the first 6 months of life. Overall, there is a decline in both any breastfeeding and exclusive breastfeeding as an infant reaches 12 months of age. However, there has been a slight increase in total breastfeeding rates from 2009 to 2016 (CDC, 2020).

2.3 Barriers and Social Support for Breastfeeding Mothers

Although predominant breastfeeding is recommended until 6 months of age, nearly 75% of mothers do not meet this recommendation (CDC, 2020). Barriers to breastfeeding include cultural influences, lack of support, socioeconomic status and education level (Office of the Surgeon General et al., 2011). It has been reported that the most common reason that mothers reported breastfeeding cessation was due to pain or discomfort, followed by infant disinterest and concern about milk supply (Scott et al., 2007). Many mothers expect breastfeeding to be easy and are unsure of how to continue when they are faced with difficulties (Office of the Surgeon General et al., 2011). In order to try to increase the likelihood that mothers will initiate and continue breastfeeding their babies, it is important for mothers to be taught how to breastfeed and be provided with support to overcome barriers.

In addition to personal concerns and problems that mothers face when trying to breastfeed, the amount and type of support a mother receives may impact her decisions about breastfeeding (Office of the Surgeon General et al., 2011; Labarere et al.,2005; Bonuck et al., 2005). An intervention study reported that mothers who attended an outpatient visit two weeks after birth with a physician who was trained in breastfeeding and counseling were more likely to report predominant breastfeeding, longer duration of breastfeeding and less problems with breastfeeding compared to those who did not attend a visit (Labarere et al., 2005). However, another study that included pre- and postnatal lactation consultant visits for mothers in the intervention group found that although there was a longer duration of breastfeeding for the intervention group compared to the control, there was no difference in the exclusivity rates (Bonuck et al., 2005). The opinions of the father, friends and other family members may also play a role in the mother's decision to breastfeed. Mothers who

have friends who have previously breastfed successfully are more likely to breastfeed compared to those who do not have friends who have breastfed their infants (Office of the Surgeon General et al., 2011).

Another important factor that influences a woman's decision to breastfeed is the mother's level of education. Mothers with a higher level of education are more likely to breastfeed (Kirkland & Fein, 2003; Celi et al., 2005), which, along with many other factors, may be attributed to the level of information that is able to be accessed. Whether this information is obtained through a physician, lactation consultant, or a class, when a mother is educated about the benefits of breastfeeding there is a significant impact on the rate of breastfeeding. Matich & Sims (1992) explored how the amount of tangible, emotional and informational support mothers received throughout pregnancy affected breastfeeding intention and implementation. Researchers found that mothers who were shown to have high amounts of informational support, moderate amounts of emotional support, and a little amount of tangible support were the most likely to breastfeed, showing the importance of knowledge on a mother's decision. However, many mothers are misinformed and lack the knowledge about the specific benefits of breastfeeding (Office of the Surgeon General et al., 2011). Findings from a national survey in 2007 showed that about 75% of the population in the US did not agree that a baby being fed human milk was less likely to get sick than one being fed formula milk, with the reason cited for disagreement being that advances in formula milk production make its health benefits equivalent to human milk (Li et al., 2007). However, it is known that formula is not equivalent to human milk (Institute of Medicine Committee on the Evaluation of the Addition of Ingredients to New Infant Formula, 2004), and that infants fed human

milk have lower incidences of infections such as upper respiratory infections, lower respiratory infections and gastrointestinal infections (Duijts et al., 2010).

Overcoming the above mentioned barriers to breastfeeding can be a challenge for mothers and therefore many mothers do not achieve the goal of exclusively breastfeeding their babies for the first six months of life. Additional challenges to breastfeeding may be faced by mothers with infants who have serious medical conditions. These mothers may experience difficulties feeding their infants, elevated maternal anxiety and lack of support (Lambert & Watters, 1998; Barbas & Kelleher, 2004). There is a paucity of research on how to best support these mothers and promote breastfeeding even though it is their children who may benefit the most from optimizing their nutrition.

2.4 Breastfeeding Infants with CHD

Historically, it was assumed that it was better to bottle-feed infants with CHD to ensure adequate nutrition and because breastfeeding was considered too laborious for such infants, putting an infant who has poor cardiopulmonary reserve under high respiratory stress (Marino et al. 1995). However, a study by Marino et al. (1995) reported that oxygen saturation levels were actually higher when infants with CHD were breastfeeding compared to when they were fed from a bottle. The same study also reported that infants with CHD had a more stable heart rate while feeding at the breast compared to a bottle, demonstrating that breastfeeding is a lot less physiologically demanding for infants with CHD than bottle feeding. Another study that followed 12 mothers throughout their breastfeeding duration reported that breastfeeding seemed to ameliorate some CHD symptoms for the infant (Lambert & Watters, 1998). It is now becoming more common for healthcare professionals to

promote breastfeeding in infants with CHD because of the knowledge that is does not compromise cardiopulmonary function and because of the health benefits of breastmilk (Stetzler et al., 2016).

Nevertheless, barriers to breastfeeding may be even more common for infants with CHD than for their healthy peers. Some of these barriers include maternal fatigue due to frequent feedings, maternal anxiety, maternal separation from the infant for medical reasons, infant fatigue and weak sucking, and problems with health care personnel and policies such as lack of privacy and perceived support (Lambert & Watters, 1998; Barbas & Kelleher, 2004). In a 2004 study that followed 68 mothers of infants with CHD throughout their breastfeeding duration, it was commonly reported that bottle feeds were given in the hospital before breastfeeding initiation was attempted and that staff did not seem to stress the importance of human milk (Barbas & Kelleher, 2004). Encouragement and consistent support and follow up from the healthcare team has been found to positively affect breastfeeding success in infants with CHD (Lambert & Watters, 1998; Stetzler et al., 2016). It is important to note that even when mothers are not able to feed their infants directly from the breast, they can be given expressed milk from a bottle or a tube (Children's Hospital of Philadelphia [CHOP], 2021). The existing research suggests that breastfeeding should be considered a medical intervention to improve feeding and growth outcomes of infants with CHD (Davis & Spatz, 2019). Combs & Marino (1993) found that the ability of an infant to breastfeed was not shown to be correlated with the type of defect, therefore, every infant with CHD should be able to attempt to breastfeed. (Davis & Spatz, 2019).

2.5 Feeding Practices in Infants with CHD

Little research has been conducted on the feeding practices of infants with CHD, and prior studies have yielded inconsistent results (Barbas & Kelleher, 2004; Rendon-Macias et al., 2002; Tandberg et al., 2010; Torowicz et al., 2015). A study in 2002 that followed 12 infants with various congenital malformations reported that the rate of exclusive breastfeeding in infants with CHD decreased from 51% shortly after birth to 7% at 6 months of age (Rendon-Macias et al., 2002). By 6 months of age, 68% of infants were being exclusively formula-fed. Mother-child separation and low birth weight were significantly and negatively correlated with exclusive breastfeeding. The perception of low milk supply was the most commonly reported reason for the cessation of breastfeeding. Although this study tracked breastfeeding practices and barriers causing changes in breastfeeding patterns, the effect of social support was not measured. The sample also included infants with other congenital malformations such as digestive and central nervous system malformations.

A study in 2004 surveyed 68 mothers of infants with CHD who had undergone cardiac surgery and found that upon discharge, 35% of their infants were being breastfed exclusively and 65% were being bottle-fed (Barbas & Kelleher, 2004). Of those being bottle-fed, 84% were bottle-fed with at least some breastmilk. The authors found that nearly half (47%) of infants received formula at some point to either increase caloric intake above what was provided with breastmilk, supplement volume of intake beyond the breastmilk supply or due to a medical reason to switch to specialty formula. There were 10% of infants who were fed formula exclusively. However, this study had a small sample size; and it was conducted in a single center that supported breastfeeding with lactation support, so the findings may not be generalizable to other settings.

A more recent study conducted in 2010 on a subsample of the Norwegian Mother and Child Cohort Study found that infants with CHD were less likely to be fed breastmilk, compared to the general healthy population at 6 months of age; and there was a faster rate of weaning for infants with comorbidities (Tandberg et al., 2010). Researchers found that 74% of infants with CHD were receiving some breastmilk at 6 months of age, compared to 84% of healthy infants (Tandberg et al., 2010). This rate is high compared to other studies, however the sample in this study included mothers who were predominantly of high socioeconomic status and education level. Therefore, the results could have overestimated breastfeeding rates due to the increased capabilities and knowledge of the mothers. Researchers also did not measure the feeding mode of the infant, so there was no information about whether mothers were breastfeeding from the breast, a bottle or a tube.

The most recent study on breastfeeding infants with CHD was published in 2015. That study followed 62 mother-infant dyads from The Children's Hospital of Philadelphia (CHOP) and reported that 89% of mothers initiated lactation for their infants (Torowicz et al., 2015). The authors also found that over 70% of the infants' diets consisted of human milk, although it was most common to feed with a bottle or through a tube rather than directly from the breast. Overall, this study showed promising success rates of human milk provision. However, the majority of the sample was ethnically white and well educated so the results may not be generalizable to other groups. The authors also mentioned that those who delivered in the CHOP special delivery unit were more likely to initiate breastfeeding because of a prenatal lactation consultation that all mothers in that unit receive. Therefore, the study's findings may

have overestimated the provision of human milk to this population. Nevertheless, the study demonstrated the importance of support on the success of breastfeeding.

The research on breastfeeding infants with CHD is limited. The few studies that have been conducted have had varied results and have lacked details on the barriers that mothers faced and the social support that mothers received throughout their breastfeeding experiences. Additionally, prior studies may not be generalizable due to their small and homogeneous samples. It is evident that although mothers of infants with CHD face additional barriers and feeding difficulties, they are able to breastfeed successfully. Therefore, it is important to understand the feeding patterns, challenges and role of social support in breastfeeding infants with CHD to improve and advise strategies for the health of mothers and infants across their lifespan and to support mothers in meeting breastfeeding recommendations.

Chapter 3

MANUSCRIPT

3.1 Background

Human milk is considered the gold standard for infant nutrition and it is recommended that infants receive human milk for the first six months of life followed by continued provision of human milk, in addition to complementary foods, through at least 12 months (AAP, 2012; Walker, 2010; World Health Organization [WHO], 2018; American Dietetic Association [ADA], 2009; NIH, 2020; Office of Surgeon General et al., 2011). Longer duration of feeding human milk has been associated with a decreased incidence of adverse health outcomes such as necrotizing enterocolitis, otitis media, and gastrointestinal, urinary and respiratory infections (Gertosio et al., 2016; Grummer-Strawn & Rollins, 2015; Ip et al., 2007). Moreover, exclusively providing human milk for the first six months of life is associated with lower infant mortality rates worldwide. (Grummer-Strawn & Rollins, 2015)

Despite the well-documented nutrition and health benefits of human milk, and the recommendations to predominantly feed infants human milk until 6 months of age (National Institute of Health [NIH], 2017; Office of the Surgeon General, 2011), only 25.6% of infants in the United States are predominantly breastfed at 6 months of age (CDC, 2020). The Surgeon General's Call to Action to Support Breastfeeding outlines the barriers that influence achievement of these recommendations, including cultural influences, lack of support, socioeconomic status and education level (The Office of the Surgeon General, 2011). Furthermore, mothers of infants with serious health

conditions face additional challenges to breastfeeding, including: maternal anxiety, separation from the infant for medical reasons, infant fatigue and weak sucking due to medical conditions, and lack of privacy in hospital settings (Lambert & Watters, 1998; Barbas & Kelleher, 2004).

Research on breastfeeding and provision of human milk to infants with congenital heart disease (CHD) is limited. A study of infants less than 6 months of age with CHD in a cardiac intensive care unit (CICU) reported that 89% of infants were fed human milk, with 13% by direct breastfeeding, 63% by bottle feedings, and 31% by gavage feeding (Torowicz et al., 2015). While this study did not report barriers to breastfeeding experienced by mothers of infants in the CICU, it did report that mothers received support for breastfeeding from International Board Certified Lactation Consultants and breastfeeding resource nurses during their stay (Torowicz et al., 2015). Further, specific to infants with cyanotic defects, Jadcherla et al. (2009) found that feeding readiness and oromotor skill delays lead to prolonged hospital stays and an increased risk of malnutrition. From the few studies of human milk feeding in infants with CHD, a better understanding of the feeding patterns, barriers to and the role of social support in breastfeeding infants with CHD is needed. The current study aims to describe the course of breastfeeding in infants with CHD from birth to 12 months of age, with a focus on breastfeeding characteristics (e.g., early lactation experiences, breastfeeding challenges, sources of breastfeeding support) and their relationship to the exclusivity and duration of feeding human milk.

3.2 Methods

3.2.1 Design

This study was a prospective, longitudinal, observational study of feeding practices, social support received, and barriers to breastfeeding experienced by mothers of infants with CHD who planned to breastfeed. The study was approved by the Institutional Review Boards of both the Children's Hospital of Philadelphia (CHOP) and the University of Delaware.

3.2.2 Setting

Data was collected on infants with CHD who were admitted to the Cardiac Intensive Care Unit (CICU) at CHOP between 2015-2018. Mother-infant dyads were followed throughout the first year of the infant's life.

3.2.3 Participants

Eligible participants were infants born full term (≥37 and ≤42 weeks gestation at birth) as a singleton, appropriate size for gestational age, diagnosed with congenital heart disease (CHD), who had undergone or had planned to undergo neonatal corrective or palliative surgery prior to discharge, and between the ages of 0-21 days old at enrollment. Eligible mothers were ≥18 years old, English-speaking, and planning to breastfeed. Infants were excluded if they had other physical, neurological, or physiological anomalies that are known to affect feeding (e.g. cleft palate or inborn errors of metabolism).

3.2.4 Data Collection

A registered dietitian nutritionist (RDN) and International Board certified lactation consultant (IBCLC), who works with maternal-infant dyads in the cardiac

intensive care unit (CICU), approached eligible mothers regarding the study. Written informed consent was obtained from mothers who agreed to participate in the study.

There were nine total study contacts, the first of which took place at 0.5 months of age (enrollment), and the remaining contacts occurred when the infant was 1, 2, 3, 4, 6, 8, 10, and 12 months of age. Study questionnaires focused on infant feeding, breastfeeding challenges, and breastfeeding support. The questions were adapted from the Infant Feeding Practices questionnaires (CDC, 2019).

3.2.4.1 Participant Characteristics

At study enrollment (0.5 months), the following infant information was collected: sex, ethnicity, race, and type of cardiac defect. Parental information collected included: maternal and paternal age, marital status, education level, maternal employment status, and participation in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) . At each visit, mothers were asked if their infant had been hospitalized in the past month. If the answer to this question was yes, the number of days the infant was hospitalized was recorded.

3.2.4.2 Breastfeeding Characteristics

Data on breastfeeding initiation (early lactation), breastfeeding challenges and breastfeeding support were first collected at study enrollment (0.5 months of age). Mothers were asked if their infants had yet been fed human milk, if they were able to hold their infant skin to skin after delivery, and how long after birth it took for their milk to come in. Data was also collected on whether mothers were able to successfully nurse at the breast and if so, how many days after delivery the first breastfeeding took place and the location that breastfeeding was initiated. Mothers were asked (‘yes’ or

'no') if they had faced any challenges breastfeeding. If 'yes', mothers reviewed a discrete list of challenges and indicated 'yes' or no' for each challenge. An 'other' option was also provided for challenges not on the discrete list. Finally, mothers were asked whether they had received any breastfeeding support in the last month. If the answer to this question was 'yes', they were asked to specify if help was from a lactation consultant, nurse, family member, doctor, friend or midwife; an open text field was also provided for mothers to note any other sources of support that were not on the discrete list.

At each subsequent visit (months 1, 2, 3, 4, 6, 8, 10, 12), mothers were queried on sources of breastfeeding support

3.2.4.3 Duration and Exclusivity of Feeding Human Milk

At each visit, data on feeding type (i.e., 'human milk only', a mix of human milk and formula milk', a mix human milk with formula powder' , 'formula milk only', or 'other dairy/non-dairy milk') was collected and infants were categorized according to feeding type. From this data, duration and exclusivity of feeding 'human milk only' and 'any human milk' were determined as continuous variables (months). 'Human milk only' refers to infants feeding human milk as a sole source of nutrition with no supplementation with infant formula or dairy/non-dairy milk. 'Any human milk' refers to infants feeding any human milk, either as a sole source of nutrition or in combination with other milk such as infant formula or dairy/non-dairy milk. Each infant was assigned a measure for both variables.

3.2.5 Data Analysis

Shapiro-Wilk tests were conducted on all outcome variables to evaluate normality. Continuous variables are reported as means (standard deviations) if normally distributed, and as median and interquartile range if not normally distributed. Categorical variables are reported as frequency and percentage. To assess associations between breastfeeding characteristics and exclusivity and duration of feeding human milk, correlation analysis was used for continuous variables. For categorical variables, hypothesis testing was the general approach with a student's t-test used to test for differences among two groups for normally distributed variables and a Mann-Whitney U test used for not-normally distributed variables; to test for differences among three or more groups, Kruskal-Wallis or analysis of variance tests were used. Statistical analysis was performed using IBM SPSS Statistics for Windows version 27 (IBM Corp., Armonk, N.Y., USA) and statistical significance was set at p-values ≤ 0.05.

3.3 Results

3.3.1 Participant Characteristics

A total of 75 mother-infant dyads were enrolled in this study. Of those, 1 infant dropped out of the study before baseline characteristics were collected resulting in a total of 74 mother-infant dyads for which data was available at the start of the study. Participant characteristics are shown in **Table 1**. The majority of infants were male, Non-Hispanic, and Caucasian. There was a similar proportion of infants with single and biventricular defects (n=41 single, n=34 bi). The number of infants that were rehospitalized at some point during the study was 53 (72%), and the mean duration of hospital stay was 8.8 days. With respect to parental characteristics, the majority of mothers and fathers had completed 1-4 years of college. The majority of mothers were

employed, married, and did not participate in the WIC program. The average age of participating mothers was 30.8 years (standard deviation [SD]=4.7) and 32.3 years (SD=5.4) for participating fathers.

3.3.2 Breastfeeding Characteristics

Characteristics of breastfeeding at enrollment (0.5 months) are shown in **Table 2**. For a majority of mothers (80%), it took 3 or more days for their breastmilk to come in. Most mothers (78%) were able to nurse at the breast during the first 0.5 months of the infant's life, with breastfeeding initiation taking place in the CICU for 81% of mothers. Challenges with breastfeeding reported at enrollment are shown in **Table 3**. The majority of mothers (93%) reported having at least one challenge, with the most common (38%) being that the baby had trouble latching. Fourteen mothers (20%) reported experiencing 4 or more challenges. Sources of support for breastfeeding received by mothers in the first 6 months are shown in **Table 4**. Most (69%) of the support received took place early in lactation; at 0.5 months of age, 38 (76%) mothers received help from a lactation consultant and 31 mothers (62%) from a nurse. Other reported sources of support included speech pathologists at the 0.5 and 1 month visits and a support group at the 3 month visit.

3.3.3 Duration and Exclusivity of Feeding Human Milk

The percentages of infants feeding 'human milk only' or 'any human milk' (either as a sole source of nutrition or in combination with other milk such as infant formula or dairy/non-dairy milk) throughout the first year of life, are shown in **Figure 1**. At baseline (0.5 months), all infants (n=74, 100%) were feeding 'human milk only' and categorized as feeding both 'human milk only' as well as 'any human milk'. At 6

months, 41 (57%) infants were feeding ‘any human milk’, with 22 (31%) of those feeding ‘human milk only’. At 12 months, 22 (31%) infants were feeding ‘any human milk’ with 11 (15%) feeding ‘human milk only’. The mean duration of ‘any human milk’ consumption, over the first year of life, was 6.4 months (interquartile range [IQR]=1-12; median=6; SD=4.51). The mean duration of ‘human milk only’ consumption over the first year of life was 3.19 months (IQR = 0.5-4, median = 0.5, SD=4.40).

3.3.3.1 Relationships Among Infant Characteristics and Exclusivity and Duration of Human Milk Feeding

None of the infant characteristics captured (sex, ethnicity, race, defect, or ever rehospitalized) were significantly associated with the duration of ‘any human milk’ or ‘human milk only’ consumption. Of the parental characteristics (maternal and paternal education, marital status, maternal employment status and WIC status) marital status (Kruskal-Wallis H=8.5; p=0.014) and paternal education (Kruskal-Wallis H=8.86; p=0.031) were significantly related to feeding ‘ human milk only’. Those who were married (median=0.75; IQR=0.5-9; mean=3.92; SD = 4.72) provided human milk for a longer duration than those who were single (median=0.50; IQR=0-1; mean=0.63; SD=1.01; Mann-Whitney U=224,5; p = 0.004). Fathers who had more than 4 years of college (median=4; IQR=0.5-12; mean= 5.82; SD=5.52) had infants feeding human milk for a longer duration than either those who had 1-4 years of college (median=0.5; IQR =0.5-3; mean=2.55; SD=4.06; Mann-Whitney U=186.5; p=0.01) or those whose education was completed at 11th or 12th grade in high school (median=0.5; IQR=0-4; mean=5.5; SD=6.36; Mann-Whitney U=43; p=0.015). However, paternal education did not remain significant with a Bonferoni adjustment of p=0.008. Duration of ‘any

human milk' consumption was significantly related to maternal education (Kruskal Wallis H=8.46; p=0.037), with those mothers whose education was completed at 11th or 12th grade in high school (median=1; IQR=1-2; mean=1.4; SD=0.894) providing human milk for a significantly shorter duration than either those who had 1-4 years of college (median=7; IQR=1-12; mean=6.58; SD=4.59; Mann-Whitney U=42.5; p=0.02; not significant with Bonferroni adjustment of p=0.008) or those who had more than 4 years of college (median=6; IQR=4-12; mean=7.52; SD=4.17; Mann-Whitney U=9; p=0.003). 'Any human milk' consumption was also significantly related to WIC status, with those who participated in WIC breastfeeding for a shorter duration (median=1; IQR=-5.5; mean=3.17; SD=3.19) than those who did not participate (median=6; IQR=2-12; mean=6.93; SD=4.48; Mann Whitney U=169.5; p = 0.009).

3.3.3.2 Relationships Among Breastfeeding Characteristics and Exclusivity and Duration of Human Milk Feeding

The following breastfeeding characteristics were not associated with the duration of 'any human milk' or 'human milk only' consumption: holding the infant skin to skin, time until milk came in, how long after delivery the infant first nursed, and the location that breastfeeding was initiated.

With respect to challenges with breastfeeding, having any challenge with breastfeeding (yes/no) was not associated with duration of 'any human milk' consumption or 'human milk only' consumption. However, duration of 'human milk only' consumption differed for mothers' reporting that their infants had trouble sucking (Mann-Whitney U=199.5; p=0.027); those who had trouble sucking (N=11; mean=4.64; SD=4.65; median=3; IQR=1-10) breastfed for longer than those who did not face this problem (N=63; mean=2.93; SD=4.37; median=0.5; IQR=0.5-4). Not

having enough milk also affected the duration of 'human milk only' consumption (Mann-Whitney U=121; p=0.035), with those who faced this problem on average feeding 'human milk only' for a shorter duration (N=7; mean=0.79 months; SD=1.44; median=0.5; IQR=0-0.5) than those who did not (N=67; mean=3.45 months; SD=4.54; median=0.5; IQR=0.5-6).

Finally, receiving support (yes/no) was not associated with the duration of feeding 'any human milk' or 'human milk only'. However, it was noted that the highest percentage of support occurred in the first month of infants' life and dropped off quickly there after (**Table 4**).

3.4 Discussion

This study demonstrated that mothers of infants with CHD were able to successfully provide their infants with human milk, despite commonly facing breastfeeding challenges and rehospitalizations.

Our study found that 14% (N=8) of mothers initiated breastfeeding within the first hour after birth. Although there is no national data available on the proportion of infants in the US who receive early initiation of human milk, the world average is 48% (United Nations International Children's Emergency Fund [UNICEF], 2020). WHO recommends to initiate within the first hour after birth in order to reduce infant mortality and facilitate emotional bonding between the mother and infant (WHO, 2020). It is also recommended that all infants be held skin to skin after birth in order to help initiate and promote breastfeeding. (Moore et al., 2016; Cleveland et al., 2017). Over half of the mothers (62%) in this study were able to have skin to skin contact with their infants following birth. Although there is no national data on the number of infants with congenital heart disease receiving skin to skin contact, the CDC reports

that 67% of infants in the US receive skin to skin contact with their mothers after birth (CDC, 2018). Other practices that promote breast milk production such as early initiation is imperative, especially given the positive relationship between adequate milk supply at 4 to 6 days and supply at 6 weeks in both preterm and term infants (Hill & Aldag, 2004).

We found that the 3 most common challenges mothers reported facing were: infant having trouble latching, infant not waking up regularly enough to nurse, and mother having overfull or engorged breasts. Another common problem, infants having trouble sucking, surprisingly resulted in a longer duration of 'human milk only' feeding than those infants who did not have this problem. Further investigation, however, found that 72% of mothers who reported this problem also reported to be tube and bottle feeding in addition to breastfeeding at the time, while the remaining 28% of mothers reported to be bottle feeding in addition to breastfeeding, suggesting that having alternate means of providing human milk is helpful for duration of feeding human milk. Further, all but one mother reported receiving help with breastfeeding at this time which demonstrates the importance of support in overcoming challenges while breastfeeding. Providing 'human milk only' was also associated with a shorter duration for mothers who reported not having enough milk. It is difficult to compare the results of this study to others, as there is a paucity of literature regarding breastfeeding challenges of mothers with infants with CHD. However, one study conducted in Brazil assessed the reasons for exclusive breastfeeding cessation, the two most common of which were CHD-related complications and, similar to the findings of this study, the mother not having enough milk (Goulart et al., 2020). In the general population, not having enough milk is a commonly reported reason for breastfeeding

cessation (Odom et al., 2013; Li et al., 2007). In the ICU setting, it is common to experience challenges with human milk expression as well. Mothers of preterm infants often report lack of privacy in an unfamiliar environment. In addition, scheduled feedings and feeding an infant connected to monitors and feeding tubes can create more barriers for mothers to meet breastfeeding and milk production goals. (Fernandez-Medina et al., 2019) Additional research in this population of infants with CHD is warranted to determine the common challenges mothers face that are associated with the cessation of human milk provision, both at home and in the CICU setting.

The support mothers received from both lactation consultants and nurses occurred early in lactation. In the general population, it is well-known that providing support increases breastfeeding exclusivity and duration (McFadden et al., 2017). Although we found no studies that explored sources of support in infants with CHD and their effect on duration of feeding human milk, we found one study that reported mothers who received prenatal lactation education were more likely to initiate and continue breastfeeding their infants with CHD (Torowicz et al., 2015; Davis & Spatz, 2019). Therefore, pre- and postnatal breastfeeding support for vulnerable populations, such as those with CHD, should be a focus of care.

The duration of ‘any human milk’ was longer than that of ‘human milk only’ and similar to rates among the general population. National breastfeeding rates reported from the CDC (2020) indicate 58% and 35% of infants are feeding ‘any human milk’ at 6 and 12 months respectively. Our study found similar percentages with 58% and 31% receiving ‘any human milk’ at 6 and 12 months, respectively.

Furthermore, nationally, 25.6% of infants were feeding 'human milk only' at 6 months, compared to 31% of infants in this sample.

This study was a novel study in that there is little research on how breastfeeding challenges and support affect duration and exclusivity of feeding human milk in infants with CHD. Moreover, this study was unique in its longitudinal design in which feeding type was assessed throughout the first year of life. This study had limitations. First, the majority of the parents had a college degree or higher making our sample more educated than that of the general US population. Additionally, we focused on the occurrence of rather than duration of early breastfeeding challenges, therefore, we were unable to determine if later challenges affected duration of human milk feeding. Future studies should examine breastfeeding challenges throughout the entire course of breastfeeding and their relation to breastfeeding cessation.

3.5 Conclusion

Our findings provide important insight into the breastfeeding experiences of mothers of infants with CHD. These mothers were able to provide human milk at rates similar to those of mothers of healthy infants. Despite this population facing additional challenges, breastfeeding infants with CHD is possible and should be encouraged and supported by healthcare providers.

Chapter 4

CONCLUSION

In conclusion, the results of this study support previous findings (Tandberg et al., 2010; Torowicz et al. 2015; Davis & Spatz, 2019) that mothers of infants with CHD are able to successfully breastfeed, despite facing additional challenges and rehospitalizations.

Mothers most commonly received breastfeeding support in the first two weeks of their infant's life from lactation consultants and nurses. Human milk durations were not significantly affected by receiving support or the majority of feeding challenges mothers faced, besides the infant having trouble sucking and the mother not producing enough milk. Infants fed 'any human milk' for an average of 6.4 months and 'human milk only for an average of 3.19 months, at rates similar to that of the general United States population (CDC, 2020).

Future studies should examine the occurrence and types of breastfeeding challenges mothers face throughout their entire breastfeeding experience and their relationship to human milk duration and exclusivity. Furthermore, feeding mode is an important factor that should be examined relating to breastfeeding duration, since providing human milk to an infant through various feeding modes can help mothers overcome breastfeeding challenges while also increasing or maintaining human milk durations.

Overall, the findings of this study provide important insight into the breastfeeding experiences of mothers of infants with CHD, including support received

and challenges faced. These mothers were able to provide human milk at rates similar to those of mothers of healthy infants despite facing additional challenges, including rehospitalizations and feeding difficulties. Breastfeeding infants with CHD is possible and should be encouraged and supported by healthcare providers in order to improve health outcomes of these mothers and their infants.

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Appendix A

TABLES

Table 1 Participant Characteristics (N=74)

Paternal Education	
12 y of high school	11 (15)
1-4 y of trade school	4 (6)

Table 2 Characteristics of Breastfeeding at Enrollment (0.5 months: *N*=74)

Characteristic	*N* (%)

Table 3 Challenges with Breastfeeding Reported at Enrollment (0.5 months; *N*=74)

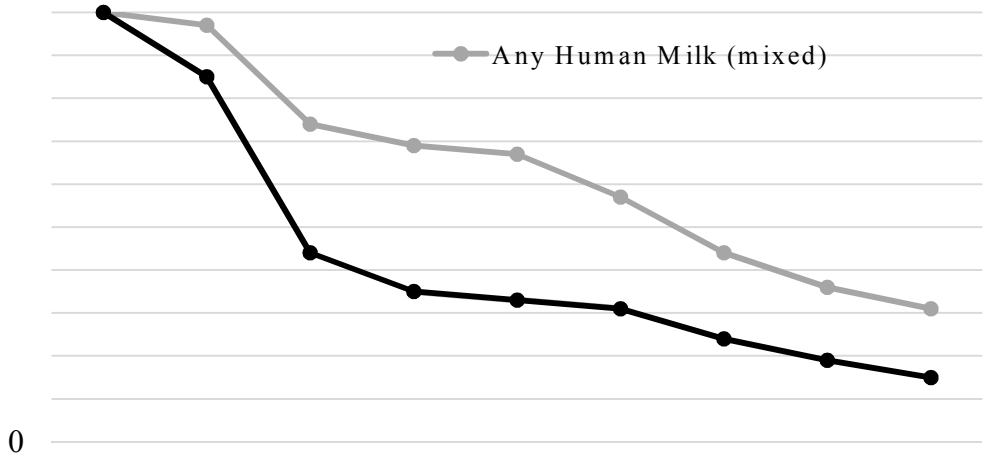
Problem Reported	N (%)

Table 4 Sources of Support Received for Breastfeeding in the first 6 months (N=74)

Appendix B

FIGURES

Figure 1: Duration and Exclusivity of Feeding Human Milk by Infant Age



One subject signed the informed consent but did not complete any questionnaires, one subject dropped out after enrollment, one subject dropped out after visit 2 while still breastfeeding so duration of breastfeeding could not be determined

Appendix C

STUDY DOCUMENTS

C.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

☐

C.4 Demographic Questionnaire

Demography: Visit 1

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

What is <u>YOUR CHILD'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*) _____

C.5 General Interview Questionnaire

General Interview Form: Visit 1

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

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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? _____

C.6 Infant Medical History Questionnaire

C.7 Infant Feeding History: Visit 1 at 2 Weeks

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._ _ _ _ _ Age_____ 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
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? _____

C.8 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._____ Age_____ 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?_____

C.9 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._____ Age_____ **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._____ Age_____ 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?_____

C.10 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._ _ _ _ _ Age_____ 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._____ Age_____ 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