2018

A retrospective study of breast milk feeding in infants with oral clefts

BOSTON UNIVERSITY

SCHOOL OF MEDICINE

Thesis

A RETROSPECTIVE STUDY OF BREAST MILK FEEDING IN INFANTS WITH ORAL CLEFTS

by

ELIZABETH MN RATHWELL

B.A., Whitman College, 2007

Submitted in partial fulfillment of the

requirements for the degree of

Master of Science

2018

Approved by

First Reader

C. James McKnight, Ph.D.
Associate Professor of Physiology & Biophysics

Second Reader

Christy McKinney, Ph.D., MPH
Associate Professor in Craniofacial Medicine, Pediatrics
Adjunct Associate Professor in Oral Health Sciences
University of Washington
Investigator, Seattle Children's Research Institute

A RETROSPECTIVE STUDY OF BREAST MILK FEEDING IN INFANTS WITH ORAL CLEFTS

ELIZABETH MN RATHWELL

ABSTRACT

Objective: The goal of this study was to gather information from mothers' of children born with orofacial clefts (OFC) in order to more accurately describe their early feeding experiences, from the time of diagnosis through the first six months of life.

Methods: We surveyed mother's whose babies with OFC were treated at Seattle Children's Hospital (SCH) Craniofacial Clinic and were born on or after 1/1/2013 through 12/31/2016. Survey questions were geared toward understanding overall difficulty with feeding, access to supplies for feeding, and methods and duration of any breast milk feeding.

Results: Eighty-two percent of mothers wanted to exclusively breastfeed for the first 16 weeks prior to the OFC diagnosis, of which 79% attempted breastfeeding and 74% attempted any breast milk feeding. Donor milk was used in 18% of mothers and 41% supplemented with formula in the delivery hospital. The majority of women were knowledgeable about facts of breastfeeding and 41% reported they received information from a lactation specialist in their delivery hospital. The level of stress reported by mothers stayed relatively the same over first 4 weeks of life and dropped by 16 weeks. The majority of women who used a breast pump pumped for 0 to 20 minutes in first week and then 0 to 30 minutes between weeks 4 to 16. Thirty percent of mothers reported receiving information specifically from a craniofacial nurse and craniofacial pediatrician

before delivery and 36% reported receiving information from a craniofacial nurse and craniofacial pediatrician after their birth hospital stay.

Conclusion: Initial study results of feeding practices, knowledge of breast milk feeding, and feeding experiences of mothers with babies born with OFCs show that most mother's intended to exclusively breastfeed prior to their birth and that the majority of women were reasonably informed about the benefits of breastfeeding. We also found that after the delivery of their child with an OFC more mothers reported having difficulty with feeding and wanted to provide breast milk longer than they were able to do so. Once the data collection is complete the survey data will be stratified for prenatal versus postnatal diagnosis and also when a breast pump was obtained. This information and additional data will be collected from a second phase of the study, which is a medical chart abstraction to look at the child's demographics and growth chart data for the first six months of life.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

CL ..... Cleft Lip

CL/P ..... Cleft Lip and Palate

CP ..... Cleft Palate

CRF ..... Case Report Form

EMR ..... Electronic Medical Record

HIPAA ..... Health Insurance Portability and Accountability Act of 1996

NAM ..... NasoAlveolar Molding

OFC ..... Orofacial Cleft

OM ..... Otitis Media

PRS ..... Pierre Roban Syndrome

SCH ..... Seattle Children's Hospital

INTRODUCTION

The Problem with Feeding Infants with Orofacial Clefts

Orofacial clefts (OFCs) are the second most common birth defects in the United States. Estimates are that 2,650 babies are born with isolated cleft palate each year and 4,440 babies are born with either cleft lip or cleft lip and palate each year.[20] The risk of being born with an OFC is estimated as 1 in 1,574 births for isolated cleft palate and 1 in 940 birth for cleft lip with or without cleft palate.[20] More boys than girls are affected by OFCs and it disproportionately affects families of low socioeconomic status (SES).[20]

OFCs are generally classified into a number of groups, which subsequently have differences in the effects on the types of problems that result with feeding babies born with OFCs. OFCs have been described anatomically, morphologically, and pathogenically. Currently the most common classification system is based on the embryology of the developing structures that includes isolated cleft palate (CP), isolated cleft lip (CL) and alveolus, and cleft lip with cleft palate (CLP). These groups are often divided into *primary palatal defects* and *secondary palatal defects*. Primary palate involvement here refers to clefts involving the lip with or without cleft palate, while secondary palate involvement refers to clefts involving the hard and soft palate only, otherwise known as an isolated cleft palate.[24] The classification systems used by clinicians and surgeons, as an example, often differ, but for the purposes of this study the general etiological classification system of OFCs described here is preferred. In our study

we have chosen to discuss the different OFCs into CL and CP/CLP phenotypes because we recognize that having involvement of the cleft palate is most problematic for feeding.

Despite the commonality in the United States of OFCs as a birth defect they are clinically very serious birth defects that have a multitude of repercussions for the health of the child. These in turn have important implications for parents and families who have a child born with an OFC. Diagnoses are made prenatally and postnatally, which creates an additional layer or complication for the family in their preparedness for having a child with a serious medical condition. Additionally the extent (e.g. the presence of a cleft palate) is often not determined until the baby is born whether or not the cleft lip was identified in the prenatal period.

Difficulties with Feeding a Child with an OFC

Establishing good feeding practices is central for any child in the early postnatal period, but this can be particularly difficult in babies born with OFCs. The extent of feeding difficulties is in large part related to the type of OFC. Children born with OFCs and more specifically their families require a considerable amount of support and education in order to understand how to feed a child with a cleft. For all newborns establishing good feeding practices is crucial, but because of their anatomical abnormality, children born with an OFC are at a much higher risk for inadequate feeding leading to decreased oral intake and poor weight gain. There is often a delay in returning to birth weight as well as development of failure to thrive, which can occur for a host of

reasons. Barzilai, et al. describes this enhanced risk for babies born with clefts as "at risk for sucking inefficiency, excessive air intake, frequent nasal regurgitation of milk, excessively long feeding times, and fatigue".[5]

Children with OFCs represent a vulnerable population that as a group experience feeding difficulties. In addition, the breadth of research done on feeding difficulties specifically in infants born with OFCs is limited, which further puts them at a disadvantage. Despite the identification of why mechanically infants born with OFCs have difficulty feeding, there are only a limited number of studies that have looked at the variability of suction and compression depending on cleft types. Reid et al demonstrated the size and location of clefts altered the intra-oral pressures and thus the levels of suction and compression generated when attempting to feed.[22] The goal of those studies[22,1,16] was to evaluate feeding difficulties in order to address better clinical management for infants with clefts.

Infants are born with biologically innate feeding instincts that allow for the feeding process of a well-latched contact with the mother that allows for a coordinated sequence in order to feed, that involves sucking, swallowing, and breathing.[4] Crucial to the success of this feeding sequence is the ability to create a vacuum or suction, which requires the latch or seal allowing for intraoral negative pressure to be generated. Depending on the type of OFC the baby can experience anywhere from little to no issues with feeding to being unable to breastfeed at all. Often babies born with CL are able to

feed without issue, however some with a CL have problems with an anterior seal around the nipple. Babies born with CP or CLP most often are unable to breastfeed because an intact palate is the key anatomical structure necessary to generate intraoral negative pressure and allow for suction.[13]

Infants born with OFCs can experience feeding difficulties to varying degrees. Some infants will be unable to breastfeed at all, while others will be able to do so sufficiently depending on the severity of the cleft as well as the degree of involvement of the primary and secondary palate. Mothers with infants that do experience difficulties breastfeeding due to the structural anomalies of the OFC often have difficulty establishing and/or maintaining their milk supply. This difficulty results because the process of milk stimulation and production requires adequate suction in order to foster correct positioning and compression of the lactiferous sinuses of the breast.[13] Correct movement and positioning of the infants tongue in accordance with the palatal structures is necessary for effective breastfeeding and can even be disrupted in infants with OFCs ranging from isolated cleft lips and small clefts of soft palate or bifid uvula.[13]

The Importance of Breast Milk

Receiving breast milk as an infant has well-established benefits[2,7], which, potentially, children with OFCs are not receiving. Breastfeeding and receiving human milk exclusively for a minimum of 6 months and up to one year with complementary foods remains the recommendation of the medical community and is strongly supported

in its benefits in the literature.[2,7,26] The multitude of health benefits, both short and long term, for the child are immense and furthermore the proportion of babies or mothers where medical contraindications for breastfeeding exist is a rarity.[2] Human milk provides nutritional, immunological and developmental benefits for infants.[6] Infants that receive breast milk and/or are breastfed are shown to have better outcomes in respiratory infections, gastrointestinal infections including necrotizing enterocolitis, Celiac disease and inflammatory bowel disease, Sudden Infant Death Syndrome and general infant mortality, development of allergies, incidence of obesity and type I diabetes, and childhood leukemia and lymphoma.[2,1,10,3] More recently there have also been studies that showed cognitive differences in neurodevelopmental outcomes, particularly in preterm infants.[9,27] However it should be noted in comparison studies between human milk and formula fed infants there is less clear research to support a direct relationship between breast milk and breastfeeding, with multiple confounding variables at play.[9]

The research on the benefits of breast milk on improving health outcomes surrounding respiratory infections and incidence of otitis media (OM, middle ear infections) is particularly strong. In particular the studies[2,19] show a correlation between duration and exclusivity of breast milk with decreased rates of hospitalization for infections, oxygen requirements, and developing OM on its own or secondary to other colds and throat infections. The outcomes can be stratified by breast milk feeding in first 2 months, 3 months, 4 months and so on showing improved health outcomes the longer

the duration.[2] This is important because children with OFCs are at increased risk of ear OM.[3,12]

Facilitating Feeding in Children with OFCs

Specialized equipment, along with education and support, are necessary for success in feeding infants with OFCs. As mentioned earlier infants born with OFCs suffer a structural malformation that may prevent effective breastfeeding to varying degrees.[4] There are a series of clinical protocols that provide guidelines for breastfeeding and bottle feeding infants with OFCs.[23] Additionally, infants with more severe OFCs, especially those involving the secondary palate, will be fed exclusively using specialized bottles and/or feeding devices, requiring those mothers to be completely breast pump dependent in order to express their breast milk for feeding purposes. Previous studies have shown that individualized and repeated assessment, education, and evaluation of feeding are necessary for parents in order to establish a successful feeding regimen for infants with OFCs.

There exists a copious amount of information about feeding an infant with a cleft that varies in its application to each individual infant. Breastfeeding in and of itself can be challenging for new mothers. In the instance of a child born with an OFC, the mothers will have additional feeding principles they will need to become familiar with in order to successfully feed their infant. These can include choosing the appropriate bottle and feeding device, assessing for adequate milk flow, recognition of signs of distress in the

infant when feeding, duration, amount and positioning during feeding, education around appropriate weight gain, and how to utilize and gain access to resources to support feeding such as obtaining feeding supplies and feeding specialists.

A number of specialized bottles have been created to aid in feeding an infant with an OFC. The most common ones are Haberman, Mead Johnson, and Pigeon. Access to other equipment necessary for feeding such as breast pumps is also a key component to successful feeding. Education by a feeding specialist on proper use of specialized bottles/feeding devices and breast pumps are paramount and often require multiple consults. In fact, consistent evaluation of the infant born with a cleft is essential to making necessary adjustments to their mode of feeding to assess for things like adequate weight gain versus failure to thrive and risk of infections secondary to aspiration from improper feeding, and so forth.

Previous studies have shown that parents have expressed consistently that the training and education on how to feed their infant born with a cleft has been insufficient. Specifically, parents expressed two main ideas—the first was not receiving enough training, education, and/or support and the second dealt with the timing of their first visit to address feeding issues.[17,11] Many mothers do not know they could potentially breastfeed their child born with an isolated cleft lip or that they could still provide breast milk for their child with a cleft.[23] Inadequate training of medical professionals and clinicians at birthing hospitals has contributed to these issues.[13]

Impact of the Timing of Diagnosis

Infants born with OFCs are diagnosed prenatally or postnatally. The timing of the diagnosis plays an important role in the method of delivery of information regarding feeding their infant. Even with prenatal diagnosis, the specific challenges of feeding are often unknown until birth or shortly thereafter since ultrasound only provides a limited view of the specific cleft and whether or not the palate is involved. Additionally there is an issue of missed diagnoses of OFCs until either birth or some time thereafter. This is especially so in instances of clefts involving the secondary palate, which are often not visible in ultrasound or at birth. It is unclear how this information delivery to moms/parents is received and if the delivery method during clinic interactions could be altered to reduce stress and improve their feeding experiences. There is an extensive literature that describes the loss and emotional difficulty experienced by parents, particularly mothers, at the time of initial diagnosis and when difficulty breastfeeding arises. This occurrence is especially true for parents of children born with OFCs. Whether they are informed prenatally or postnatally that their child has an OFC, mothers express feelings of increased stress regarding how they will feed their infant and what new and unexpected challenges they may now face.[17,11] Additionally successful feeding of an infant is a crucial element to the development of the early maternal-child relationship.[25] Parents of infants born with an OFC are concerned not only about the efficiency of feeding, but also the safety and increased responsibility of caring for a child with special healthcare needs. This added stressor can have long-lasting effects on the well-being of the family as a whole, particularly at the already vulnerable time of the newborn period.[15]

Prior Research on Feeding Infants with an OFC

The Alperovich et al study[17] was one of the only studies to look at the relative rates of breast milk feeding that occurred in infants born with OFCs in the United States. There is a gap in the literature in understanding how parents with infants diagnosed with OFCs are given information and training around feeding their infant and after delivery what percentage of infants are fed breast milk, by what method and for how long, in order to compare these rates to noncleft infants. Given the wealth of data that supports breast milk feeding benefits for infants with OFCs, study's like the Alperovich study aimed to understand the rate of infants with clefts receiving these benefits of breast milk feeding even in the instances when breastfeeding was not an option. The study consisted of a questionnaire for parents that asked questions to gather information on specific cleft diagnosis and whether this occurred prenatally or postnatally, the instruction and education parents received including the data behind the benefits of infants receiving breast milk, and then information about whether or not their infant received breast milk and the specifics of this including method of delivery, duration, proportion of feeds exclusively breast milk, and all of this was in relation to the timing of the NasoAlveolar Molding (NAM) treatment in preparation for their first cleft surgery.

Results of the Alperovich study found that 67.3% of patients received breast milk for some period of time.[17] This was stratified by before, during, and after NAM treatment. The specialized Haberman bottle was the most common method for breast milk delivery at 75%. Parents reported (84%) receiving instruction and education (termed

"counseling") about feeding their infant with a cleft and those that did were "significantly more likely to give breast milk to their infant compared to parents who did not receive any"—72% versus 44%.

The Alperovich study was important because it was one of the first studies that put the emphasis on what infants with clefts are fed, e.g. breast milk. Previous studies about addressing feeding difficulties in infants with clefts by in large instead put the emphasis on how they are fed and overcoming the challenges of failure to thrive and poor growth. As such, Alperovich notes that comparison data was for their study was limited since most other studies considered the method of feeding infants with clefts, but not what was being fed to infants with clefts.

The Purpose of the Seattle Children's Feeding and Cleft Project

We need to better understand the methods (milk delivery) and duration of feeding children with OFCs. Given the dearth of knowledge, we set out to better understand the mother's experience surrounding feeding her child with an OFC. We were interested in getting a better understanding about the feelings and expectations mothers had prior to their child's diagnosis with a cleft and understanding the timing of both the diagnosis and subsequent feeding education and advice related to feeding. Similarly we are interested in learning more about the knowledge base of the benefits of breast milk feeding that mothers have in general. Our hypotheses are: (1) the intention to breastfeed is positively associated with duration of breast milk expression and breast milk feeding; (2) mothers

who receive a breast pump prior to delivery will breast milk feed for a longer duration compared to those who receive a breast pump after first 24 hours after delivery; (3) mothers given hospital grade breast pump will have the longest duration of breast milk feeding; (5) there will be no significant difference between a prenatal or postnatal OFC diagnosis on mother's knowledge about evidence-based benefits of breast milk; and (6) mothers that choose to breastfeed or breast milk feed will incur more stress with feeding than those using formula.

METHODS

Study Design

We are conducting a study (IRB Study #: STUDY00000541) to learn about the mother's experience with early feeding of her child with an oral cleft and how it varies by cleft type. We conducted a retrospective cohort study of mothers who gave birth to a child diagnosed with an OFC. The exposures of interest were time of diagnosis (pre or postnatal) and type of cleft (CL versus CP/CLP). The outcomes were related to the mother's experience. This study is currently in process and the methods described here include the entire study plan, elements of which are not discussed in the Results section. Our hypotheses that (1) mothers with a prenatal diagnosis will have a better feeding experience than those with a postnatal diagnosis and that (2) infants with CL will have fewer feeding problems than infants with CP/CLP are not evaluated in this thesis because the numbers were too small and the data were not yet collected. Therefore this thesis focuses on the descriptive aspects of the project.

Recruitment and Enrollment

The identified population for study were the mother's and infant patients seen at SCH Craniofacial Clinic.

Pre-Screening for Eligibility: Inclusion and Exclusion Criteria

Mothers eligible for our study must meet the following inclusion criteria:

Mother is at least 18 years of age; Child has diagnosis of an OFC; Child is seen as a patient at the SCH Craniofacial clinic; Child is either born on or after January 1, 2013 and up to and including December 31, 2016.

Mothers will not be eligible for our study if they demonstrate any of the following exclusion criteria: Child is diagnosed with Pierre Robin Syndrome (PRS); Child has a history of receiving nasogastric feeds that were managed/continued at home or child has a history of gastrostomy tube placement within the first six months of life; Child is adopted, in foster care, or otherwise not with their biological mother; Mother does not speak/read enough English in order to be consented and/or complete the study survey.

Final Eligibility Screening and Recruitment

Mothers who meet pre-screening eligibility are mailed an introduction recruitment packet that includes the following: An introduction letter explaining our study with pertinent contact information; A response form which they can mail back indicating whether or not they are interested in learning more about the study, as well as preferred times to be contacted; Copies of the HIPAA consent form and our study specific consent form, which they will need to complete to be consented into our study and prior to completing the survey.

Two weeks from the date the packets were sent we began initiating calls to reach out to eligible participants in order to explain the study, address any questions/concerns they

have, and to also assess final inclusion/exclusion criteria—(1) the mother is at least 18 years of age and (2) the mother is proficient enough in speaking/reading English in order to complete the study. Neither of these elements is reliably or consistently monitored as part of the electronic medical record (EMR).

Study participants received compensation as a thank you for their willingness to participate in the study. They were sent gift cards in the amount of $20 to be given one time after the consent and completion of the survey.

Consent

Mothers who agree to be in the study provide an up-to-date email address, which gets logged in our tracking sheet. The participants are then sent an email invitation from REDCap[21] that includes an individualized web link specific to them which gives them access to three documents: (1) Health Permission Form (first consent, standard HIPPA); (2) Consent form (second consent, study specific); and (3) Oral Cleft Feeding Survey (web-based survey tool). The software formulates it so each participant must complete form (1) before they can move onto form (2) and finally form (3). This ensures that they fully complete our online consent process before participating in our survey tool. (Form (1) *Permission to Use, Create and Share Health Information for Research* can be found in Appendix 1; Form (2) *Parental Permission Form: Consent Form Ages 18 and Up* can be found in Appendix 2; Form (3) *Oral Cleft Feeding Survey* can be found in Appendix 3).

Data Collection Instruments

Web-based Survey

Our web-based survey (Appendix) is the tool we are using to collect the retrospective data from our mothers. The Oral Cleft Feeding Survey has four sections and takes about 15-20 minutes to complete. An option for a phone conducted survey was given to those study participants who prefer it. This tool was created using HIPPA compliant REDCap software and the data collected is stored within this server. Reports are generated from this for data analysis.

Our study research team, which includes members with expertise in feeding and caring for children with OFCs, created the survey tool together. Our research team consists of co-Principal Investigators Christy McKinney PhD, MPH and Emily Gallagher MD, MPH whose role was to oversee the project, including our data collection tools, and perform statistical analyses with the help of collaborators Babette Seibold PhD who helped perform the statistical analyses, and Robin Glass OT, IBCLC and Ashli Brown RN, BSN, CMN who provided expertise on infant feeding; and a Clinical Research Assistant position (performed by Elizabeth Rathwell, BA) who performed chart abstraction, conducted all elements of recruitment, any necessary follow-up, and managed study activities. All research study team members are involved in the development and authorship of the manuscript for publication.

The survey questions themselves are grouped into four sections: (1) We ask questions about prior birth and the mothers birth experience of their child with an OFC; (2) feeding questions that include both breast milk and formula feeding, types of milk expression, and duration of; (3) previous knowledge surrounding feeding their child and guidance they may have received prior to the birth of their child; and (4) the last section aims to gather standard demographic data about mother and baby. In our survey we make a distinction between breastfeeding and receiving breast milk, which is termed *breast milk feeding*.

Medical Chart Abstraction

The Medical Chart Abstraction form can be found in Appendix 4. This Case Report Form (CRF) form was created to abstract necessary data from the EMR of the patient after their mother had consented online. The data collected included clinical and demographic characteristics of the child and growth chart data from visits to the Craniofacial Clinic. We used this data abstraction tool in order to gather the cleft phenotype and timing of OFC diagnosis, which are two key elements to our stratified analysis. Basic demographic information (e.g. date of birth, race/ethnicity) is obtained and relevant parameters for the patient's treatment plan, such as gestational weight at birth, date of initial visit and prenatal visit when applicable, and timing of repair surgeries.

The growth chart data includes weight, length, head circumference (OFC) and weight for length. These measures are taken beginning with their first initial visit to the SCH Craniofacial Clinic and spaced out monthly after that up to the first six months of life. There is variation in the measurements available given that some children are seen much more frequently than others, often due to participation in pre-surgical molding protocols or if they had additional medical issues, for example failure to thrive. Additionally percentages and z-scores were abstracted along with data points.

Analytic Plan

We generated descriptive statistics for the currently enrolled study participants. We calculated means, medians, and percentages of responses in order to describe our study population of mothers whose children are patients at SCH Craniofacial Clinic.

RESULTS

In this pilot study we identified 424 potentially eligible patients from a database provided by and maintained by the SCH Craniofacial Center. At this time 224 possible participants were screened and of that total 146 were eligible based on the screening criteria. We have 46 study participants that were successfully recruited and completed surveys for an overall response rate of 31%. These study participants were recruited typically by phone or a combination of phone and email. The average age of our mothers was 30.5 years (range 23.3—37.7 years) (Table 1). At the time of the survey the majority were either married or cohabitating (85%) with a mean of 4.5 household members. Mothers level of education ranged from General Education Diploma to 4-year college; nearly half had a 4-year college degree (46%) and reported a household income of $50,000—$99,999 (46%). English was the primary language spoken at home (62%). 59% had private insurance at the time their baby with an OFC was born compared to 28% Medicaid and 8% with some sort of military insurance. Survey participants were predominantly white (85%) and the remaining identified as Asian or American Indian/Alaskan Native (Table 1).

There were more vaginal deliveries (72%) compared to cesarean sections (27%). Just over half (54%) of our study participants had an epidural, which is slightly below the United States national average of 61%.[18] A quarter (26%) reported that two weeks after their baby was born, a healthcare provider was concerned about how much weight their

baby had lost. Medical conditions that could potentially cause delivery complications or feeding issues were tracked with a small number of mothers reporting hypertension, gestational diabetes, and preeclampsia as the only issues. The majority of OFC babies were skin-to-skin with their mothers in the first 24 hours after birth (90%) and 31% of babies were transferred and spend some time in the NICU or special care nursery. Mothers took an average of 10.5 weeks of maternity leave after their baby with an OFC was born (Table 1).

Table 1. Demographics, Baseline and Delivery Characteristics of Mother

Table 1. Demographics, baseline and delivery characteristics of Mother	
Mother	Value (SD)
Age, mean	30.5 (7.2)
Mother	Value (% of Responses)
Marital status	
Married/living with partner	33 (85%)
Single/never married	2 (5%)
Divorced/separated	2 (5%)
missing	2 (5%)
Mother, highest level of education	
<High school	0 (0%)
High school / GED	11 (28%)
Technical college / 2 year degree	8 (21%)
4-year college degree+	18 (46%)
	2 (5%)
Insurance	
Private	23 (59%)
Private + Medicaid	
Medicaid (Apple care, CHIP)	11 (28%)
Military	3 (8%)
Other	0 (0%)

missing	2 (5%)
Income, categories	
$0 - $19,999	5 (13%)
$20,000 - $49,999	6 (15%)
$50,000 - $99,999	18 (46%)
Parity (median)	1.1 (1.1)
Proportion of prior births ever breastfed	0.8 (0.4)
Duration of breastfeeding prior babies (mean)	9.9 (8.9)
# in household	4.5 (1.2)

Survey Questions	Total (% of Responders)
Race	
White	33 (85%)
Asian	2 (5%)
Black	0 (0%)
Native American	0 (0%)
Other	3 (8%)
Delivery and perinatal characteristics of child with an oral cleft	
Method of delivery	
Vaginal	27 (69%)
C-section	10 (26%)
Other assisted delivery	0 (0%)
Missing	2 (5%)
Delivery complications, % yes	
Hypertension	4 (10%)
Gestational diabetes	6 (15%)
Diabetes diagnosed before pregnancy	0 (0%)
Preeclampsia	3 (8%)
Increased amniotic fluid	0 (0%)
Epidural, % yes	21 (54%)
Baby in NICU/special care nursery, % yes	12 (31%)
Baby at breast or skin-to-skin in first hour after birth, % yes	35 (90%)
Provider concerned baby not back to birth weight at 2 weeks	10 (26%)
Duration of maternity leave, weeks	10.5 (5.8)

Overwhelmingly the intent prior to diagnosis was to exclusively breastfeed (82%) (Table 2). Similarly 31 mothers (79%) attempted to breastfeed their child at some point, which we defined as child was fed breast milk directly from their breast. The mean number of hours old when the baby was first breastfed was 5.5 hours (19.8 median). Over 40% received formula supplementation during their hospital stay. Well over half of the mothers attempted some form of breast milk feeding (74%) and donor milk (18%) was also used by some mothers, as part of breast milk feeding. Over half used bottles to feed their babies breast milk, either their own or donor milk. Over half (54%) of mother's reported they were *very disappointed* when they learned they would be unable to breastfeed. Mother's stress levels, on a 0 to 100 scale with 100 being highly stressful to feed their baby reported the following levels at 1 week (57.5), 4 weeks (47.3), and 16 weeks (24.0). The majority of women were knowledgeable about the facts and benefits of breastfeeding, which were asked in TRUE/FALSE questions and the percentage reported are those that answered *YES/TRUE* (Table 2).

Table 2. Mother's Experience with Early Feeding and Knowledge of Breastmilk Benefits

Table 2. Mother's experience with early feeding and knowledge of breastmilk benefits	
Survey Questions	Total (% of Responders)
Breastfeeding and breast milk feeding	
Planned method of feeding for first 16 weeks prior to diagnosis	
Breastfeed exclusively	32 (82%)
Formula feed	2 (5%)
Breastfeed and formula feed	3 (8%)

missing	2 (5%)
Breastfeeding	
Any breastfeeding, % yes	31 (79%)
Infant age at time you first breastfed baby (hours, mean)	5.5 (19.8)
Any bottle feeding with breast milk (own or donor), % yes	24 (62%)
Breast milk feeding	
Any breast milk feeding, % yes	29 (74%)
Donor milk	
Any donor breast milk feeding, % yes	7 (18%)
Duration of any donor milk feeding, weeks, mean	18.6 (19.9)
Formula / supplementation in hospital stay, % yes	16 (41%)
Stress in feeding baby	
1 week after birth	57.5 (38.1)
4 weeks after birth	47.3 (35.8)
16 weeks after birth	24.0 (31.6)
Feeling when learned they may not be able to breastfeed baby	
Not disappointed	1 (3%)
Somewhat disappointed	7 (18%)
Fairly disappointed	2 (5%)
Very disappointed	21 (54%)
Unsure/other	6 (15%)
Mother's knowledge re: breastfeeding, % yes	
Skin-to-skin helps establish breast milk supply	35 (90%)
Hand expression in first hour helps establish milk supply	30 (77%)
Pumping in first 24 hours helps establish milk supply	32 (82%)
Babies who breastfeed gain more weight faster	10 (26%)
Breast milk reduces respiratory infection	31 (79%)
Babies who breastfeed are taller	2 (5%)
Breast milk reduces otitis media	30 (77%)
Breastfeeding reduces breast cancer	21 (54%)

Only 10% of mothers used a breast pump prior to delivery (Table 3). The majority first used a breast pump within the first 24 hours after birth (38%). About half (56%) first pumped when their baby was between 2 to 48 hours old and none within the first hour. In total 49% of mothers pumped during their delivery hospital stay prior to going home (Table 3).

Table 3. Mother's Experience with Expressing Breastmilk, Receiving Guidance, and Accessing Breast Pumps

Table 3. Mothers experience with expressing breastmilk, receiving guidance and accessing breast pumps	
Variables	Total (% of Responders)
Expression of breast milk	
Hand Expression	
Hand expressed breast milk first time	
Prior to delivery	4 (10%)
≤1 hour after birth	4 (10%)
2-24 hours after birth	11 (28%)
≥24 hours after birth	7 (18%)
Breast Pump Use	
Infant age at time you first pumped breast milk	
≤1 hour after birth	0 (0%)
2-48 hours after birth	22 (56%)
3-7 days after birth	6 (15%)
7-14	1 (3%)
≥14	2 (5%)
Pumped breast milk during hospital stay, %yes	19 (49%)

Mother's frequency of breast pump use (Table 4) was reported at number of times in a 24-hour period stratified by the following levels at 24 hours, 1 week, 4 weeks, and 16 weeks. One-third of mothers reported pumping 0-1 times in the first 24 hours, which was the largest group. About one-quarter pumped 8+ times/day in both 1 week (28%) and 4 weeks (26%) after birth. By 16 weeks just under half of the women reported pumping 4-7 times/day (42%) (Table 4).

Table 4. Frequency of Breast Pump Use

Frequency of pumping at	0-1 Times	2-3 Times	4-5 Times	6-7 Times	8+ Times	missing
24 hours after birth	13 (33%)	4 (10%)	3 (8%)	4 (10%)	6 (15%)	9 (23%)
1 week after birth	5 (13%)	1 (3%)	7 (18%)	7 (18%)	11 (28%)	8 (21%)
4 weeks after birth	3 (8%)	7 (18%)	2 (5%)	9 (23%)	10 (26%)	8 (21%)
16 weeks after birth	7 (18%)	4 (10%)	8 (21%)	8 (21%)	4 (10%)	8 (21%)

The duration of breast pump use (Table 5) per session was reported in minute increments at the same timing levels as above. One-third (31%) pumped between 0-10 minutes in the first 24 hours after birth, about half (54%) pumped somewhere between 10-30 minutes in the first week, about one-quarter pumped for 10-20 minutes, 20-30 minutes, or >30 minutes, and finally about half (44%) pumped between 0-minutes by 16 weeks (Table 5).

Table 5. Duration of Breast Pump use

Duration of pumping at	0-10 minutes	10-20 minutes	20-30 minutes	>30 minutes	missing
24 hours after birth	12 (31%)	11 (28%)	7 (18%)	1 (3%)	8 (21%)
1 week after birth	6 (15%)	9 (23%)	12 (31%)	4 (10%)	8 (21%)
4 weeks after birth	3 (8%)	11 (28%)	9 (23%)	8 (21%)	8 (21%)
16 weeks after birth	8 (21%)	9 (23%)	7 (18%)	7 (18%)	8 (21%)

In the first 24 hours after birth, 57% reported breastfeeding was frequently or always difficult (Figure 1). At 1 week, 41% reported breastfeeding was frequently or always difficult and this decreased to 5% by 16 weeks feeding their baby with an OFC, as well as for some a forfeiture of breastfeeding. In contrast 90% reported none to occasional difficulty in feeding by 16 weeks after birth (Figure 1). The percentage of mother's exclusively breastfeeding was also stratified by timing at 24 hours, 1 week, 4 weeks, and 16 weeks (Figure 2) and shows that the proportion of women breastfeeding only changed significantly over time for those who reported 0% or 100%. The number of women providing 75-100% of feedings with breast milk initially increased then declined over time. The number of women providing 0% of feedings with breast milk steadily declined over time from 12 women down to 3 women (31% to 8%) (Figure 2).

Figure 1. Reported Level of Difficulty with Breast Feeding

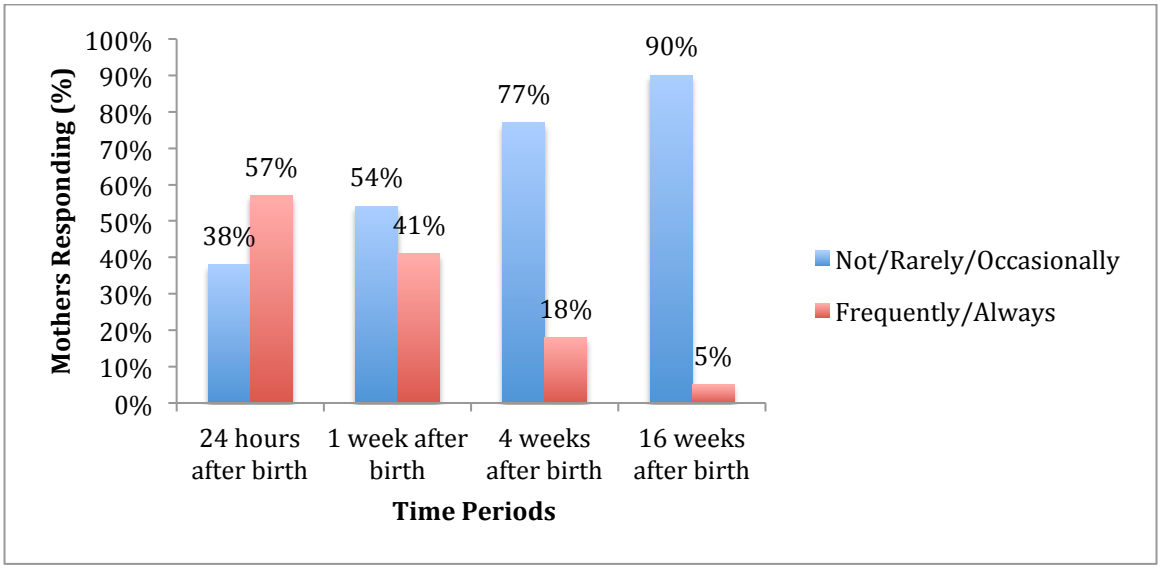
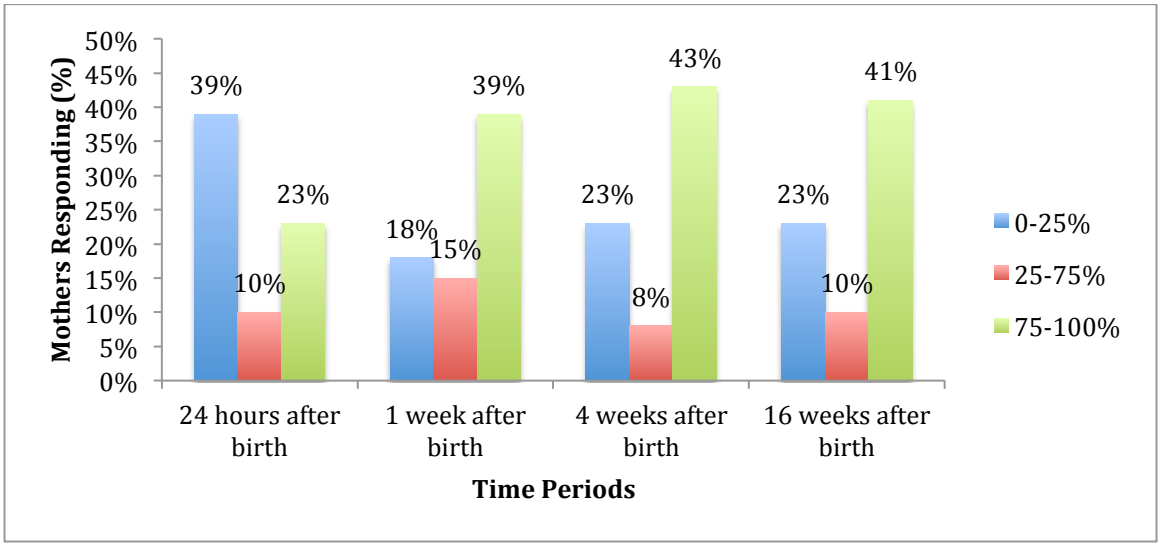


Figure 2. Proportion of Exclusive Breast Milk Feedings*



***There were missing data where respondents left question blank, value which are not represented in this figure. 24 hrs (28%), 1 wk (28%), 4 wks (26%), 16 wks (26%).**

The majority of mother's received guidance on feeding their infant by a lactation specialist in the hospital (41%) (Table 6). Interaction with a craniofacial nurse mostly occurred before delivery (15%) with prenatal diagnoses and during the first week after being discharged home from the hospital (21%) with either pre- or postnatal diagnoses. The number of women who had contact with a general pediatrician stayed the same during each time period reported (Table 6). Respondents expressed a series of reasons for breast pump cessation with many respondents electing more than one contributing factor (Table 7). Thirty-five women (90%) selected *preferred to use formula* as one of the reasons for no longer pumping. Mother's also selected *stopped producing breast milk* (72%) and *tired of pumping* (72%), while 59% reported they would have preferred to have given breast milk longer than they were able to. Just over half (62%) were still pumping some amount at 16 weeks after birth (Table 7).

Table 6. Guidance Provided By Healthcare Providers

Provider who provided guidance (not mutually exclusive)	Yes			
	Before delivery	During the birth hospital stay	After birth hospital stay, first week of life	After birth hospital stay after first week
Delivery nurse	1 (3%)	6(15%)	3 (8%)	2 (5%)
Lactation specialist	2 (5%)	16(41%)	4(10%)	5 (13%)
Craniofacial nurse	6 (15%)	0	2 (5%)	8 (21%)
General pediatrician	4 (10%)	4(10%)	4(10%)	4 (10%)
Craniofacial pediatrician	6 (15%)	0	2 (5%)	9 (23%)

Table 7. Mother's Experience Expressing Breastmilk with Breast Pump

Insurance covered some or all of the cost, % yes	6 (15%)
Cost paid out of pocket in the first 16 weeks ($, mean, SD)	70.2 (146.1)
Still pumping at 16 weeks, % yes	24 (62%)
Wanted to provide breastmilk longer than able, % yes	23 (59%)
Reason stopped pumping	
Stopped producing breastmilk	28 (72%)
Tired of pumping	28 (72%)
Preferred to use formula	35 (90%)
Returned to work	33 (85%)
Other	21 (54%)

When given the opportunity to provide direct feedback a large proportion of mother's provided free text responses, many of which highlighted their increased stress and lack of support in feeding their infant with an OFC (excerpts below).

"We need to educate LCs about craniofacial abnormalities, feeding and exclusive pumping. With a birth defect as common as cleft palate, there should be a lot more immediate support in place."

"There is not nearly enough support for breastfeeding mom's of cleft babies, especially ones that travel for their babies care."

"Adjusting to not being able to nurse was most difficult as baby fed well with bottle. Having to pump (while baby often was crying in first few weeks) in order to have bottle

available took adjustment to have milk ready ahead, yet still needing to pump when baby cried/was hungry."

DISCUSSION

This study set out to survey mothers with children born with orofacial clefts in order to learn about their experiences surrounding feeding their infant. We found that by in large mother's intended to exclusively breastfeed prior to their birth and that the majority of women were reasonably informed about the benefits of breastfeeding. We also found that after the delivery of their child with an OFC most mothers reported having difficulty with feeding and wanted to provide breast milk longer than they were able to.

Our results demonstrate that women who have babies born with an OFC most often do feel a sense of loss and disappointment when they have difficulty or are unable to breastfeed their child. The mother's do in fact experience stress in feeding their child, particularly in the first 16 weeks of life. This is important because this can lead to babies born with OFCs consequentially receiving less breast milk, either by lower rates and/or duration of breastfeeding or breast milk feeding. According to the CDC's *Breastfeeding Report Card* the national average in 2016 of babies that were ever fed breast milk in any amount or duration is 81.1%[7] compared to our response rate of 79%. While these values may seem very similar, they do not tell us anything about the proportions of feeding or duration. The same CDC report shows 44.4% of babies nationwide were exclusively breastfed at three months of age and 22.3% at 6 months of age, while 51.8% continued breastfeeding at six months of age and 30.7% at 12 months of age. These values are almost certainly much higher in the non-cleft population than they would be for the

mothers in this study and others with babies with OFCs. Also concerning is the national average of formula supplementation within the first two days of life has been steadily declining for non-cleft babies since 2007 and is most recently reported in 2014 at 15%[8] compared to our response of 41% of mother's with babies born with OFCs receiving formula supplementation in first few days of life. These trends highlight the increased feeding difficulty for babies born with OFCs face and indicate more work needs to be done in looking at the trained medical providers that are providing education, support, and resources for mothers', which is substantiated by feedback we received in our surveys.

Each element of the study's hypothesis and specific aims cannot be fully discussed here given that the data collection portion of the study is on going. The medical chart abstraction data has not been compiled yet. This is an initial report and that data will be added at the conclusion of the study. The initial results of this study highlight the willingness of mother's with children with OFCs to provide feedback related to feeding their infant. The issue lies not in finding willing participants, but rather in the recruitment methods and challenges inherent in successfully contacting study participants retrospectively after the very busy time period of having a newborn, particularly where the majority likely experienced feeding issues given the difficulty with feeding a child with an orofacial cleft anomaly. Additionally the more time that passed after the birth of their child contributed to errors in the EMR as it pertained to contact information (e.g. addresses not up-to-date).

Extensive recruitment efforts were made to get into contact with eligible study participants. The initial data collected thus far is rich and provides important information that is otherwise not represented in the craniofacial literature. As previously mentioned there are numerous studies in which the mechanics of how to feed a child with an OFC are discussed, but there is much more limited data on how much, how often, and by what method mother's are choosing to attempt to breast milk feed their infant. Replications of this study in its entirety at other sites and among a group of infants unaffected by orofacial clefts for additional comparison are important next steps. This will only be possible if more studies involving children with OFCs are done. There already exists a large swath of studies on breastfeeding and breast milk feeding in different groups, including healthy babies and preterm babies, but these studies as previously mentioned have rarely extended to babies with OFCs. Given the strong evidence-based data on benefits of breast milk feeding it follows that understanding where changes to or new clinical interventions, and perhaps collaboration between birthing hospitals and craniofacial clinics, can be made would make a significant impact on the health outcomes of children born with OFCs and their mother's.

Our preliminary data aligns with previous studies that described the stress and emotional components a mother feels when unable to breastfeed her infant, both in the loss felt from being unable to breastfeed as well as increased stress with the new challenges and safety considerations in feeding their infant with an OFC.[25,15,17,11] As

reported in the results, mother's by in large described the difficulty level and stress of feeding declined by 16 weeks of life compared to the beginning. The decrease in perceived difficulty level could be due to improved skills and experience in feeding their baby with an OFC, as well as due to some forfeiture of breastfeeding.

The responses from mother's regarding their knowledge of breast milk expression, establishing a breast milk supply, and the benefits of breastfeeding prior to delivery indicates there existed general knowledge about breast milk and feeding. The interest here lies in how this knowledge did or did not inform/help mothers when it came to feeding their infant with an OFC. Given this preliminary data on relative stress, difficulty level, and duration of feeding there is evidence that perhaps the increased challenges of feeding a children with an orofacial cleft disrupted the feeding practices (including intentionality) and success mothers had prior to delivery.

Matrices questions were used to ascertain the frequency (Table 4) and duration (Table 5) of breast pump use. There are larger proportions in both tables of *missing* data, which can possibly be attributed to those respondents who never used a pump and therefore the skip pattern in the survey recorded their responses as blank/missing, when in fact the question did not apply to them. The values in these tables are useful in mapping the breast pumping practices of mother's attempting to feed breast milk to their babies with an OFC. The literature on feeding children with OFCs offers numerous clinical recommendations on pumping practices and general guidelines on best practices

in order to establish milk supply. Understanding more about how mother's with children with clefts used breast pumps contributes greatly to understanding possible areas for improvement with clinical interventions with the goal of increasing breast milk received by infants born with clefts.

Upon completion of the study and additional data elements of medical chart abstraction a more in-depth statistical analysis will be performed. The addition of infection rates and growth chart data will provide key findings not described in detail elsewhere in the literature surrounding feeding children with OFCs. This initial reporting of our study provides necessary first steps in understanding the typical duration of breast milk feeding and the barriers experienced by mothers attempting to feed their child with a cleft. Using the descriptions by mothers of their stress and difficulty with feeding from this study can be used to inform the clinical practices, recommendations, and support provided to mothers and families to help improve the feeding experience and outcomes in children with orofacial clefts.

APPENDIX

(1) Health Permission Form

Permission to Use, Create and Share Health Information for Research

Permission to Use, Create and Share Health Information for Research Study Title:

Early Feeding Study of Children with Orofacial Clefts Consent Form

IRB Study #: STUDY00000541

The federal Privacy Rule protects your/your child's health information. The Privacy Rule is part of the Health Insurance Portability and Accountability Act (HIPAA).

If you agree to take part in this research study (named above), the researchers may use, create or share your/your child's health information as part of the research. The researchers will do so **only** if you give permission to use, create or share your/your child's health information as part of the research. This form gives you information to help you decide if you will give such permission. **Please read this form carefully.** After reading this form, you can refuse to sign this form.

What does "health information" include? It includes:

- Name
- Address
- Social Security Number
- Medical and/or birth history
- Demographic information
- Results of physical exams
- Interview and/or focus group data
- Survey and/or questionnaire data
- Results of behavioral tests
- Information in your medical record relevant to this study

What the researchers may do with health information

Researchers may create new health information about you/your child during the study. Researchers may use health information in your/your child's records.

Researchers may also share health information about you/your child collected during the study with the following:

1. The sponsor of this study and its representatives.
Sponsor Name: **Seattle Children's Research Institute**

2. Researchers at other centers taking part in this research study.
Name(s) of other centers: **N/A**
3. Government agencies, ethics review boards, data and safety monitoring boards, and others responsible for watching over the safety, effectiveness, and conduct of the research.
4. Your health care providers involved in your/your child's care.
5. Other health care providers involved in your/your child's care.
6. National Institutes of Health and its grant holders for the purpose of research administrative activities (e.g., tracking overall research activity).
7. Others, as provided by law.

The Privacy Rule applies to doctors, hospitals and other health care providers.

Research Records
You may look at or copy the information that may be used or disclosed. However, for certain types of research studies, some of the research records may not be available to you/your child while the study is going on. This does not affect your right to see what is in your/your child's medical (hospital) records.

The researchers may publish or present the research findings. You/your child will not be identified in any findings that are published or presented.

The federal Privacy Rule does not apply to health information that is not identified in any way. The researchers may decide to remove any information that could identify you/your child. If they do this, the information may be used and shared by the researchers and the sponsor as the law allows. This may include use in other research studies.

Permissions to Take Part in Research

If you agree to take part or allow your child to take part in the research, you will be asked to sign a **research consent form.** The research consent form gives you details about the research. The consent form describes the risks and benefits of the research. It explains the purpose of the study, what will happen and other important information for you to know.

To be in this research study, you must also sign this permission form (Permission to Use, Create and Share Health Information for Research). If you do not want to sign this permission form, this will not affect the care and treatment you or your child receive.

How Long does the Permission Last? What if You Change Your Mind?

This permission will not expire, but you may cancel it at any time.

If you change your mind and want to cancel your permission, please let us know in writing. Write to Principal Investigator(s) (PI)/Researcher:

Christy McKinney PhD, MPH

Seattle Children's Research Institute 2001 8th Avenue, Office 632, Seattle, WA Seattle, WA 98121 christy.mckinney@seattlechildrens.org

OR

Emily Gallagher MD, MPH
Seattle Children's Hospital Craniofacial Center 4800 Sand Point Way NE, Seattle, WA 98105
emily.gallagher@seattlechildrens.org

If you cancel your permission and you/your child are a patient at Children's,

please send a copy of your letter to:

Director of Health Information and Privacy
Health Information Management
M/S OC.6.820
Seattle Children's
4800 Sand Point Way NE
Seattle, WA 98105-0371

If you cancel your permission, no other health information about you/your child will be collected for this research. However, the health information that was received with your permission may be shared or used. For example, researchers may need to use or share this information:

- for safety reasons;
- to verify the research data;
- if required by law.

If you agree to take part or allow your child to take part, you will be given a copy of this permission form after you have signed it.

Permission

By typing in my full name (below) I agree to the use, creation, and sharing of my or my child's health information for purposes of this research study. For Children's patients, your medical record # will be recorded on this form and used to place a copy of this form in your medical record.

_____ (Name)

(2) Consent Form

PARENTAL PERMISSION FORM
CONSENT FORM: Ages 18 and up

Study Title: A Retrospective Study of Breast Milk Feeding Children with Oral Clefts

Principal Researchers: Christy McKinney, PhD, MPH and Emily Gallagher, MD, MPH

The Research Team:

Name/Degree		**Phone Number**	**E-mail**
Christy McKinney, PhD, MPH		206-884-0584	christy.mckinney@seattlechildrens.org
Emily Gallagher, MD, MPH		206-987-2208	emily.gallagher@seattlechildrens.org
Robin Glass, MS, OTR, IBCLC		206-987-3138	robin.glass@seattlechildrens.org
Alan Waite		206-884-4232	alan.waite@seattlechildrens.org
Elizabeth 'Betsy' Rathwell	206-414-9113	elizabeth.rathwell@seattlechildrens.org	

If you have questions about your rights as a research study participant, you can call the Institutional Review Board at (206) 987-7804.

1. Researchers' Statement:

You have the option to take part in a research study. The goals of this form are to give you information about what would happen in the study if you choose to take part and to help you decide if you want to be in the study.

Feel free to take notes or write questions about any part of this form.

Parents/Guardians: You have the option of you and your child joining a research study. This is a parental permission form. It provides a summary of the information the research team will discuss with you. If you decide that you and your child can take part in this study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy for your records.

The word **"you"** in this form refers to you and/or your child with an oral cleft.

2. What you should know about this study:

- This form explains what would happen if you join this research study.

- Please read it carefully. Take as much time as you need.
- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study any time.
- If you choose not to be in the study, it will not affect your care at Seattle Children's.
- If you say 'Yes' now, you can still change your mind later.
- You can quit the study at anytime.
- You would not lose benefits or be penalized if you decide not to take part in the study or to quit the study later.

3. What is the goal of this study?

The goal of any research study is to answer questions. We (the research team listed on the front of this form and our staff) are doing this research study to answer three questions:

1) To learn about mothers' access to breast pumps as well as to learn about how long the baby was fed breast milk.
2) To learn about the stress, parent satisfaction and knowledge with the early family feeding experience, particularly as it relates to breast milk feeding.
3) To learn about the association between how long babies were fed breast milk and the infections and growth in babies with oral clefts.

4. Why do I have the option of joining the study?

You have the option to take part in this research study because you fit the following criteria:

- Mothers ≥18 years of age
- Child diagnosed with an orofacial cleft
- Child is patient at SCH Craniofacial Center
- Child born on or after 1/1/2013 and up to and including 12/31/2016

You would not be allowed to participate if either of the following is true:

- Child diagnosed Pierre Robin Syndrome (PRS)
- Child with a history of nasogastric feeds managed at home or gastrostomy tube
- Child is adopted

5. How many people will take part in the study?

We think that about 200 mother/infant pairs will take part in this research study at Seattle Children's.

6. If I agree to join this study, what would I need to do?

Explanation of Research Tests or Procedures:

- Web or phone-based survey (takes approximately 20 minutes to finish)
- Data collection from patient records

7. How long would I be in the study?

In the survey, we will ask questions primarily about feeding. Topic areas include whether you fed breast milk to your baby, pumping your breast milk, the benefits of breast milk, challenges you faced feeding your baby, the type of bottle or device you used to feed your baby, infections and your demographic information. The types of data we will collect from your child's medical record include the type of cleft, if your baby had a syndrome, and your baby's growth, and treatments.

If you choose to take part in all the study visits, you would be in the study for the length of time needed to fill out the survey and for the study team to collect data from patient records.

If you join the study, you can decide to stop **at anytime for any reason**. If you decide to leave the research, there are no consequences at all. If you decided to stop, you would need to talk with Dr. McKinney's research team so you leave the study in a safe way.

The research study doctor could also decide to take you out of this study. This might happen if you choose not to answer any of the survey questions. If we ask you to leave the study, we would always explain why and whether there are any steps we need to take to move you off the study.

8. What are the potential harms or risks if I join this study?

There is a risk that your confidentiality or privacy could be breached. This would mean that someone other the research team or our collaborators may find out that you were in the research or see your answers or medical information. However, we will take every precaution to make sure that this does not happen.

9. What are the potential benefits if I join this study?

Potential Benefits for You:
We do not expect this study to benefit you.

Potential Benefits for Others:
We hope to use information we get from this study to benefit others who have children with oral clefts.

10. What other options do I have?

If you choose not to be in this study, that is fine, you can simply choose not to respond. Please talk to your doctor or the research team if you have questions about this option.

11. What about confidentiality and privacy?

If you join the study, we will keep your information confidential as provided by law.

You have certain privacy rights with regards to your health information, and only with your permission may we collect, use, or share your health information for this study. The following

describes the type of information the study will create, use or share, who may use it or share it, and the purposes for which it may be used or shared.

This information may include things like:

- Past or future medical records,
- Research records, such as surveys, questionnaires, interviews, or self-reports about medical history,
- Medical or laboratory records related to this study, and
- Information specific to you like your name, address, or birthday

This information may be used by or shared with:

- Researchers (such as doctors and their staff) taking part in this study here and at other centers,
- Research sponsors – this includes any persons or companies working for, with, or owned by the sponsor,
- Review boards (such as Seattle Children's Institutional Review Board), data and safety monitoring boards, and others responsible for watching the conduct of research (such as monitors),
- Governmental agencies like the U.S. Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS), including similar agencies in other countries, and
- Public health authorities to whom we are required by law to report information for the prevention or control of disease, injury, abuse, or disability.
- If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

This information may be used or shared to:

- Complete and publish the results of the study described in this form,
- Study the results of this research,
- Check if this study was done correctly, and
- Comply with non-research obligations (if we think you or someone else could be harmed-).

You may look at or copy the information that may be used or disclosed. However, for certain types of research studies, some of the research information may not be available to you during the study. This does not affect your right to see what is in your medical (hospital) records.

There is no time limit for the use or sharing of your information. Researchers continue to analyze data for many years, and it is not always possible to know when they will be done. If your information will be banked as part of this study, it may be used in the future for other research. We would not ask for your permission prior to this future research.

Your permission for the use or sharing of your information will not expire, but you may cancel it at any time. You can do this by notifying the study team in writing. If you cancel your permission, no new information will be collected about you, but information that has already been collected may still be used and shared with others.

The use or sharing of your information will follow privacy laws, but these laws only apply to doctors, hospitals, and other health care providers. Some people who receive your health information as part of this study may share it with others without your permission if doing so is permitted by the laws they must follow.

If the results of the study are published, information that identifies you would not be used.

Your permission is documented by signing this form below. If you decide that we cannot use or share your information, you cannot participate in this study.

12. Would it cost me money to be in the study?

If you take part in this study, there would be no cost to you and no cost to your insurance company.

13. What if I were injured because I joined the study?

If you think you have been harmed from this study, please call Dr. McKinney or Dr. Gallagher using the information found on page 1 of this form.

14. Would I be paid if I join this study?

You will be paid $20 in the form of a gift card to take part in this study.

15. Who do I contact if I have problems, questions or want more information?

If I have questions or would like to know about …	You can call …	At …
• **Emergencies** • **General study questions** • **Research-related injuries** • **Any research concerns or complaints**	**Christy McKinney**	**Phone:** 206-884-0584
• **Your rights as a research participant** • **Study questions, concerns or complaints.** • **Contacting someone outside of study team**	**Institutional Review Board** This is a group of scientists and community members who make sure research meet legal and ethical standards.	**Phone:** (206) 987-7804

16. If I join the study, can I stop?

Yes. Taking part in research is always a choice. If you decide to be in the study, you can change your mind at any time. We ask that you tell Dr. McKinney or Dr. Gallagher (see page 1 for contact information).

If you choose to leave the study, it will not affect your care at Seattle Children's. You will not lose any benefits or be penalized if you choose to leave the study.

17. What would my signature on this form mean?

Your signature on this form would mean:

- The research study was explained to you.
- You had a chance to ask all the questions you have at this time. All your questions have been answered in a way that is clear.
- You understand that the persons listed on this form will answer any other questions you may have about the study or your rights as a research study participant.
- **You have rights as a research participant. We will tell you about new information or changes to the study that may affect your health or your willingness to stay in the study.**
- By signing this consent form, you do not give up any of your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
    - You agree to take part in the research study.
    - If the person reading this form is a parent/guardian, you agree to have your child take part in this research study.
    - You permit the creation, use, and sharing of your health information for the purposes of this research study as described in Section 11 above.

Please Note: If the person taking part in this research study is a foster child or a ward of the state, then please tell the researcher or their staff.

_____

Typed Name of Research Participant into REDCap

[Date and time stamped automatically in REDCap database when name entered]

(3) Oral Cleft Feeding Survey

Confidential

Oral Cleft Feeding Survey

This survey asks questions about your baby born with an oral cleft. If you have more than one baby born with an oral cleft, please answer these questions about your baby born most recently with an oral cleft. There are 4 sections to this survey. We estimate it will take you about 20 minutes to complete.

If you need to stop part way through the survey, go to the end of the survey and click on "Save and Return Later". You can click on the link to the survey in the email we sent you at any time to return to the survey. Please complete the survey in the next two weeks.

SECTION 1. PRIOR BIRTHS AND BIRTH EXPERIENCE OF CHILD WITH AN ORAL CLEFT

The first few questions are about prior births and breastfeeding your babies prior to having a child with an oral cleft.

Before your baby was born with an oral cleft, how many live births did you have? _____ (# of prior live births)

How many of your prior babies were breastfed OR received expressed breast milk? _____ (# of prior live births breastfed)

How many months did you breastfeed your baby? _____ (months)

How many months did you breastfeed your first baby? _____ (months)

How many months did you breastfeed your second baby? _____ (months)

How many months did you breastfeed your third baby? _____ (months)

How many months did you breastfeed your fourth baby? _____ (months)

How many months did you breastfeed your fifth baby? _____ (months)

How many months did you breastfeed your sixth baby? _____ (months)

How many months did you breastfeed your seventh baby? _____ (months)

How many months did you breastfeed your eighth baby? _____ (months)

The rest of the questions in this survey are about your most recent child born with an oral cleft.

During your pregnancy with your child born with an oral cleft did you have any of the following medical conditions?

	Yes	No	Don't know
Hypertension or high blood pressure	○	○	○
Gestational diabetes	○	○	○
Diabetes diagnosed before pregnancy	○	○	○
Preeclampsia	○	○	○
Increased amniotic fluid	○	○	○

What type of delivery did you have?

○ Vaginal
○ Cesarean
○ Other

Specify: _____

Did you receive an epidural?

○ Yes
○ No

How much did your baby weigh when he/she was born?

○ < 5 lbs 8 oz
○ Between 5 lbs 8 oz and 8 lbs 13 oz
○ More than 8 lbs 13 oz
○ Don't know

Two weeks after your baby was born, was a healthcare provider concerned about how much weight your baby lost?

○ Yes
○ No
○ Don't know / Unsure

What was the gestational age in weeks and days of your baby when he/she was born?

_____
(gestational age in weeks and days)

Was your baby ever cared for in a special care nursery or NICU?

○ Yes
○ No

Why was your baby in the special care nursery or NICU? _____

How many days old was your baby when your baby left the birth hospital?

_____
(days old)

Did you work outside the home after your baby was born?

○ Yes
○ No

How many weeks off work did you take after your baby was born?

_____
(weeks off)

SECTION 2: FEEDING

Was your baby at the breast or skin-to-skin in the first hour after birth?
- ◯ Yes
- ◯ No

The following questions are about BREAST FEEDING (not including pumped breast milk).

Was your child ever breastfed? That is, did your child ever receive breast milk directly from your breast?
- ◯ Yes
- ◯ No

How many hours old was your baby the first time you breastfed your baby?

_____ (hours old)

What proportion of your feedings were BREASTFEEDING at the following times. Do not include feeding your breast milk with a bottle or other device, using formula or other types of milk or nutrition.

	0%	1-25%	25-50%	50-75%	75-99%	100%
At 24 hours after birth	◯	◯	◯	◯	◯	◯
At 1 week after birth	◯	◯	◯	◯	◯	◯
At 4 weeks after birth	◯	◯	◯	◯	◯	◯
At 16 weeks after birth	◯	◯	◯	◯	◯	◯

Did your child receive formula during their hospital stay?
- ◯ Yes
- ◯ No

The following questions are about BREAST MILK FEEDING. This is when you pump your breast milk and feed your own breast milk to your baby with a bottle or other device (tube, syringe).

Was your child ever fed your breast milk using a bottle or other device?
- ◯ Yes
- ◯ No

What proportion of feedings were your PUMPED BREAST MILK at these times. Do not include breastfeeding at the breast.

	0%	1-25%	25-50%	50-75%	75-99%	100%
At 24 hours after birth	◯	◯	◯	◯	◯	◯
At 1 week after birth	◯	◯	◯	◯	◯	◯
At 4 weeks after birth	◯	◯	◯	◯	◯	◯
At 16 weeks after birth	◯	◯	◯	◯	◯	◯

The following questions are about DONOR BREAST MILK.

Was your child ever fed donor breast milk using a bottle of other device?
- ◯ Yes
- ◯ No

How many weeks did your child receive donor breast milk?

_____
(# of weeks received donor milk)

The next questions are about the types of BOTTLE OR DEVICE you used to feed your baby. How did you feed your baby at the following times? Check ALL that apply.

	Breast	Mead Johnson Squeeze bottle	Dr. Brown bottle with cleft valve	Haberman bottle	Pigeon bottle	Other device (e.g. syringe)
At 24 hours after birth	☐	☐	☐	☐	☐	☐
At 1 week after birth	☐	☐	☐	☐	☐	☐
At 4 weeks after birth	☐	☐	☐	☐	☐	☐
At 16 weeks after birth	☐	☐	☐	☐	☐	☐

The next set of questions are about your FEEDING EXPERIENCE with your baby.

Before you learned that your baby was diagnosed with an oral cleft, did you intend to breast milk or formula feed your baby in the first 16 weeks after birth?
- ◯ Breast milk feed exclusively
- ◯ Formula feed
- ◯ Breast milk and formula feed

How long did you intend to feed your baby breast milk exclusively?

_____

How long did you intend to breast milk feed before you started using formula?

_____

After birth did you (mother) have any health conditions resulting in your health care provider telling you not to breastfeed or give breast milk to your baby?
- ◯ Yes
- ◯ No
- ◯ Prefer not to answer
- ◯ Don't know

Why where you told not to breastfeed or give breast milk?

_____

How DIFFICULT was it to feed your baby at the following times?

	Not difficult at all	Rarely difficult	Occasionally difficult	Frequently difficult	Always difficult
At 24 hours after birth?	○	○	○	○	○
At 1 week after birth?	○	○	○	○	○
At 4 weeks after birth?	○	○	○	○	○
At 16 weeks after birth?	○	○	○	○	○

On a scale of 0 to 100, how STRESSFUL was it to feed your baby in the FIRST week of life?

0 50 100

(Place a mark on the scale above)

On a scale of 0 to 100, how stressful was it to feed your baby in the first FOUR weeks of life?

0 50 100

(Place a mark on the scale above)

On a scale of 0 to 100, how stressful was it to feed your baby in the first SIXTEEN weeks of life?

0 50 100

(Place a mark on the scale above)

Which of the following best describes how you felt when you learned that you may not be able to breastfeed your baby?

- ○ Not disappointed
- ○ Somewhat disappointed
- ○ Fairly disappointed
- ○ Very disappointed
- ○ Not applicable / Unsure

What would have helped you be more prepared to feed your baby? _____

Please share anything else you would like to about feeding your baby with an oral cleft in the first 16 weeks of his/her life? _____

The next set of questions are about your experience EXPRESSING BREAST MILK after birth using your hand or a breast pump.

Did you ever express your breast milk or colostrum with your hand without the baby at the breast?

- ○ Yes
- ○ No

When did you first express your breast milk by hand?

- ○ Before birth
- ○ In the first hour after birth
- ○ 2 to 24 hours after birth
- ○ More than 1 day after birth
- ○ Don't know

Did you ever express breast milk with a breast pump?

- ○ Yes
- ○ No

When did you first pump breast milk after your baby was born?

- ○ < =1 hour after birth
- ○ 2-48 hours after birth
- ○ 3-7 days after birth
- ○ 7-14 days after birth
- ○ >14 days after birth
- ○ Don't know

Did you pump breast milk during the birth hospital stay?

- ○ Yes
- ○ No

The next questions are about the FIRST breast pump you used after you left your birth hospital stay.

At the time you left the birth hospital, did you have a breast pump to use at home?
◯ Yes
◯ No

How many days old was your baby when you first used this breast pump at home?
_____
(baby's days old when got pump)

How many weeks old was your baby when you stopped using this breast pump?
_____
(baby age in weeks when stopped using first pump)

Did your insurance cover some or all of the cost of this breast pump?
◯ Yes
◯ No

What was the total amount you paid out of pocket to use this breast pump in the first 16 weeks?
_____
(total cost in $)

Did the first pump have an electric plug or batteries?
◯ Yes
◯ No

Which of the following is most like the FIRST breast pump you used most of the time to pump your breast milk in the period right after your birth hospital stay?

[Attachment: "Final REDCap Electric Breast Pumps.pdf"]

Based on the pictures, which of the following is most like the breast pump you used most of the time to pump your breast milk in the period right after your birth hospital stay?
◯ 1. MEDELA Pump-In-Style
◯ 2. MEDELA Symphony
◯ 3. NATURE'S BOND
◯ 4. SPECTRA S2 Electric
◯ 5. SPECTRA Dew 350
◯ 6. TOMY Quiet Expressions Double Electric
◯ 7. AMEDA Purely Yours
◯ 8. AMEDA Platinum
◯ 9. AMEDA Elite
◯ 10. LANSINOH SignaturePro Double Electric
◯ 11. FREEMIE Freedom
◯ 12. HYGEIA Enjoye

Which of the following is most like the breast pump you used most of the time to pump your breast milk in the period right after your birth hospital stay?

[Attachment: "Final REDCap Manual Breast Pumps.pdf"]

Based on the pictures, which of the following is most like the breast pump you used most of the time to pump your breast milk in the period right after your birth hospital stay?
◯ 1. MEDELA Harmony
◯ 2. SPECTRA Handy Manual
◯ 3. AMEDA Manual
◯ 4. LANSINOH Manual
◯ 5. FREEMIE Equality
◯ 6. HYGEIA EnHande Manual
◯ 7. HYGEIA Two Hand Manual
◯ 8. PHILLIPS Avent Comfort

Did you use any other breast pump in the first 16 weeks of your baby's life?
◯ Yes
◯ No

How many weeks old was your baby when you started using this pump?
_____
(baby age in weeks when started using next pump)

How many weeks old was your baby when you stopped using this breast pump?
_____
(baby age in weeks when stopped using second pump)

Did your insurance cover some or all of the cost of the breast pump?
- ◯ Yes
- ◯ No

What was the total amount you paid out of pocket to use this breast pump in the first 16 weeks?

_____
(total amount in $)

Did this pump have an electric plug or batteries?
- ◯ Yes
- ◯ No

Which of the following is most like the additional breast pump you used most of the time to pump your breast milk in the period right after your birth hospital stay?

[Attachment: "Final REDCap Electric Breast Pumps.pdf"]

Based on the pictures, which of the following is most like the breast pump you used most of the time to pump your breast milk in the period right after your birth hospital stay?
- ◯ 1. MEDELA Pump-In-Style
- ◯ 2. MEDELA Symphony
- ◯ 3. NATURE'S BOND
- ◯ 4. SPECTRA S2 Electric
- ◯ 5. SPECTRA Dew 350
- ◯ 6. TOMY Quiet Expressions Double Electric
- ◯ 7. AMEDA Purely Yours
- ◯ 8. AMEDA Platinum
- ◯ 9. AMEDA Elite
- ◯ 10. LANSINOH SignaturePro Double Electric
- ◯ 11. FREEMIE Freedom
- ◯ 12. HYGEIA Enjoye

Which of the following is most like the breast pump you used most of the time to pump your breast milk in the period right after your birth hospital stay?
- ◯ MEDELA Harmony Breast Pump
- ◯ SPECTRA Handy Manual Breast Pump
- ◯ AMEDA Manual Breast Pump
- ◯ LANSINOH Manual Breast Pump
- ◯ FREEMIE Equality Pump
- ◯ HYGEIA EnHande Manual Breast Pump
- ◯ HYGEIA Two-Hand Manual Breast Pump
- ◯ PHILLIPS Avent Comfort Manual Breast Pump

The next questions are about the time you spent pumping.

How many TIMES PER DAY did you express breast milk with ANY breast pump in the following times:

	0-1	2-3	4-5	6-7	8+
At 24 hours after birth	◯	◯	◯	◯	◯
At 1 week after birth	◯	◯	◯	◯	◯
At 4 weeks after birth	◯	◯	◯	◯	◯
At 16 weeks after birth	◯	◯	◯	◯	◯

How many MINUTES in a session did you typically express breast milk with ANY breast pump at the following times:

	0-10 minutes	10-20 minutes	20-30 minutes	>30 minutes
At 24 hours after birth	○	○	○	○
At 1 week after birth	○	○	○	○
At 4 weeks after birth	○	○	○	○
At 16 weeks after birth	○	○	○	○

Were you still pumping when your baby was sixteen weeks old?
- ○ Yes
- ○ No

Why did you stop pumping your breast milk? Check ALL that apply.
- ☐ I stopped producing breast milk
- ☐ Tired of pumping
- ☐ Preferred to use formula
- ☐ Returned to work
- ☐ Other
- ☐ Don't know

Specify: _____

Did you want to provide breast milk for longer than you were able to?
- ○ Yes
- ○ No

Please tell us anything else you would like to about pumping breast milk for your baby: _____

SECTION 3. GUIDANCE AND KNOWLEDGE

After your baby was diagnosed with an oral cleft, did you receive information on breastfeeding or breast milk feeding your baby from a healthcare provider?
- ○ Yes
- ○ No

Please check the providers you received advice from on breastfeeding, breast milk feeding, bottle feeding or other feeding after your baby was diagnosed with an oral cleft:
- ☐ Delivery nurse
- ☐ Lactation specialist
- ☐ Craniofacial nurse
- ☐ General pediatrician
- ☐ Craniofacial pediatrician
- ☐ Other
- ☐ None
- ☐ Don't know

Specify: _____

When did you receive advice from the Delivery Nurse? Check all the times you received advice.
- ☐ Before delivery
- ☐ During birth hospital stay
- ☐ After birth hospital stay during the baby's first week of life
- ☐ After birth hospital stay after the baby's first week of life

When did you receive advice from the Lactation Specialist? Check all the times you received advice.
- ☐ Before delivery
- ☐ During birth hospital stay
- ☐ After birth hospital stay during the baby's first week of life
- ☐ After birth hospital stay after the baby's first week of life

When did you receive advice from the Craniofacial Nurse? Check all the times you received advice.

- ☐ Before delivery
- ☐ During birth hospital stay
- ☐ After birth hospital stay during the baby's first week of life
- ☐ After birth hospital stay after the baby's first week of life

When did you receive advice from the General Pediatrician? Check all the times you received advice.

- ☐ Before delivery
- ☐ During birth hospital stay
- ☐ After birth hospital stay during the baby's first week of life
- ☐ After birth hospital stay after the baby's first week of life

When did you receive advice from Craniofacial Pediatrician? Check all the times you received advice.

- ☐ Before delivery
- ☐ During birth hospital stay
- ☐ After birth hospital stay during the baby's first week of life
- ☐ After birth hospital stay after the baby's first week of life

When did you receive advice from the [Other Provider]? Check all the times you received advice.

- ☐ Before delivery
- ☐ During birth hospital stay
- ☐ After birth hospital stay during the baby's first week of life
- ☐ After birth hospital stay after the baby's first week of life

The next set of questions are about your knowledge about breast milk expression, establishing a breast milk supply and the benefits of breastfeeding. Just answer what you think is true or false.

	True	False
Skin-to-skin contact just after birth helps to establish breast milk supply.	○	○
Hand expression in the first hour after birth helps to establish breast milk supply.	○	○
Pumping in the first 24 hours after birth helps to establish breast milk supply.	○	○
Babies who receive breast milk gain more weight faster.	○	○
Babies who receive breast milk are less likely to develop respiratory tract infections.	○	○
Babies who receive breast milk are taller than babies who do not receive breast milk.	○	○
Babies who receive breast milk are less likely to develop ear infections.	○	○

Mothers who breastfeed are less likely to develop breast cancer later in life.	○	○

The following questions are about infections and dental visits of your child with an oral cleft.

Was your child diagnosed with ANY infections in the first 16 weeks of life?
- ○ Yes
- ○ No

Which of the following infections did your child have in the first 16 weeks of life? CHECK ALL THAT APPLY.
- ☐ Otitis Media / Ear infection
- ☐ Respiratory infection / Cold
- ☐ Gastroenteritis / Vomiting / Diarrhea
- ☐ Other

Specify: _____
(describe type of infection)

Was your child prescribed a course of antibiotics to treat ANY of their infections?
- ○ Yes
- ○ No

How many courses of antibiotics did your child take in the first 16 weeks of life? _____

Would you be willing to participate in a study about your child's dental health? The study would include a complimentary general dental exam at ages 1, 2, and 3.

(Note: We are not doing the study now but may in the future.)
- ○ Yes
- ○ No

SECTION 4. YOU AND YOUR BABY'S DEMOGRAPHICS

What is your date of birth? _____

What is your current marital status?
- ○ Married
- ○ Living with partner
- ○ Single/Never married
- ○ Divorced/Separated

What is your highest level of education?
- ○ Less than high school
- ○ High school or general equivalent degree (GED)
- ○ Associates degree
- ○ Vocational/trade program
- ○ College degree
- ○ Post-graduate degree (Masters or beyond)

When your baby with a cleft was born what type of insurance did you have related to your birth? Check ALL that apply.
- ☐ Private insurance
- ☐ Medicaid
- ☐ Apple Care
- ☐ CHIP or Child Health Insurance Plan of Washington
- ☐ Medicare
- ☐ Tricare/Military families
- ☐ Other

Specify: _____

What is your race? You may check more than one box.

☐ White
☐ Asian or Pacific Islander
☐ Black
☐ American Indian or Alaskan Native
☐ Other

Specify: _____

What is your ethnicity?

◯ Hispanic
◯ Non-Hispanic

What is the primary language you speak at home?

◯ English
◯ Spanish
◯ Other

Specify: _____

How many people live in your household?

◯ 0 ◯ 1 ◯ 2 ◯ 3
◯ 4 ◯ 5 ◯ 6 ◯ 7
◯ 8 ◯ 9 ◯ 10 ◯ 11
◯ 12 ◯ 13 ◯ 14 ◯ 15
◯ 16 ◯ 17 ◯ 18 ◯ 19
◯ 20

What is your annual household income?

◯ $0 - $19,999 ◯ $20,000 - $49,999
◯ $50,000 - $99,999 ◯ $100,000+

Where did you live most of the time in your child's first 6 months of life? Please provide City, State. _____

Please tell us anything else you would like to share with us.

_____

Thank you for participating in our survey! We truly appreciate the time you have taken to answer our questions. Your input will help us provide better feeding support to children with oral clefts, their mothers and families in the future. This is only possible because people like you take the time to help us.

(4) Medical Chart Abstraction Form

MEDICAL RECORD ABSTRACTION FORM

Study: A Retrospective Study of Breast Milk Feeding Children with Oral Clefts

Section I: Abstraction Details

STUDY ID:	
CHART ABSTRACTER INITIALS:	DATE ABSTRACTED: DAY/MONTH/YEAR

Section II: Clinical & Demographic Characteristics of Child

INFORMATION ABOUT CHILD	
1. WHAT IS THE SEX OF THE CHILD?	☐ MALE ☐ FEMALE
2. WAS THE BABY A MULTIPLE?	☐ YES ☐ NO
3. WHAT TYPE OF MULTIPLE WAS THE BABY?	☐ TWIN ☐ TRIPLET ☐ QUADRUPLET OR MORE
CLEFT PHENOTYPE	
4. DOES THE CLEFT INVOLVE THE LIP?	☐ YES ☐ NO
5. WHERE IS THE CLEFT LIP LOCATED?	☐ LEFT ☐ RIGHT ☐ BILATERAL
6. DOES THE CLEFT INVOLVE THE PALATE?	☐ YES ☐ NO – SKIP TO 8
7. TYPE OF CLEFT PALATE	☐ HARD PALATE ☐ SUBMUCOUS ☐ SOFT PALATE ☐ PALATE NOT SPECIFIED
SYNDROME	
8. DOES THE BABY HAVE A DOCUMENTED SYNDROME DIAGNOSIS?	☐ CONFIRMED ☐ SUSPECTED/UNDER STUDY ☐ NONE – SKIP TO 10
9. DESCRIPTION OF THE SYNDROME	DESCRIPTION:

OR SUSPECTED SYNDROME	
10. WHAT IS THE CHILD'S RACE/ETHNICITY?	☐ WHITE, NON-HISPANIC ☐ HISPANIC, ANY RACE ☐ BLACK, NON-HISPANIC ☐ ASIAN OR PACIFIC ISLANDER ☐ AMERICAN INDIAN OR ALASKA NATIVE ☐ MULTIPLE RACES ☐ OTHER ☐ PREFERRED NOT TO ANSWER/DENIED/MISSING
PRE-SURGICAL MOLDING	
11. DID PATIENT HAVE PRE-SURGICAL MOLDING?	☐ YES ☐ NO – SKIP TO 22 ☐ DON'T KNOW – SKIP TO 22
12. TYPE	☐ LIP TAPING ☐ NAM ☐ SAM
13. START DATE	DAY/MONTH/YEAR
14. END DATE	DAY/MONTH/YEAR
15. WAS ANY OTHER TYPE OF PRE-SURGICAL MOLDING USED?	☐ YES ☐ NO – SKIP TO 22
16. TYPE	☐ LIP TAPING ☐ NAM ☐ SAM
17. START DATE	DAY/MONTH/YEAR
18. END DATE	DAY/MONTH/YEAR
19. TYPE	☐ LIP TAPING ☐ NAM ☐ SAM
20. START DATE	DAY/MONTH/YEAR
21. END DATE	

	DAY/MONTH/YEAR
22. WHAT WAS THE DATE OF LIP REPAIR SURGERY?	DAY/MONTH/YEAR
23. WERE THERE ANY OTHER SURGERIES IN THE FIRST 6 MONTHS OF LIFE?	☐ YES ☐ NO – SKIP TO 26
24. TYPE OF SURGERY	
25. DATE OF SURGERY	DAY/MONTH/YEAR
INFORMATION FROM SCH CRANIOFACIAL VISITS	
26. WHAT IS THE CHILD'S BIRTHDATE?	DAY/MONTH/YEAR
27. WAS THE MOTHER SEEN FOR A PRENATAL VISIT AT SCH CRANIOFACIAL CENTER?	☐ YES ☐ NO
28. WHAT WAS THE DATE OF THE CHILD'S FIRST VISIT TO THE SCH CRANIOFACIAL CENTER VISIT?	DAY/MONTH/YEAR
29. WHAT WAS THE CHILD'S GESTATIONAL AGE AT BIRTH?	WEEKS
30. WHAT WAS THE CHILD'S BIRTH WEIGHT?	KILOGRAMS OR LBS/OUNCES

REFERENCES

1. Alperovich, M, Frey, J, Shetye, P, Grayson, B, and Vyas, R. 2016, Breast milk feeding rates in patients with cleft lip and palate at a North American craniofacial center, *The Cleft Palate-Craniofacial Journal*, v. 54, p. 334-337.

2. American Academy of Pediatrics. 2012, Breastfeeding and the use of human milk, *Pediatrics*, v. 129:3, p. e827-e839.

3. Aniansson, G, Svensson, H, Becker, M, and Ingvarsson, L. 2002, Otitis media and feeding with breastmilk of children with cleft palate, *Journal of Plastic Reconstruction Surgery and Hand Surgery*, v. 36, p. 9-15.

4. Arvedson, JC. 1993, "Feeding infants with craniofacial anomalies." In: Arvedson, JC, Brodsky, L, 2nd edn, *Pediatric swallowing and feeding: assessment and management*, Singular Publisher, Canada, p. 527-561. Print.

5. Barzilai, J. 2005, Feeding 101. *Presented at the 62nd Meeting of the American Cleft Palate-Craniofacial Association*. Myrtle Beach, SC.

6. Callen, J and Pinelli, J. 2005, A review of the literature examining the benefits and challenges, incidence and duration, and barriers to breastfeeding in preterm infants, *Advanced Neonatal Care*, v. 5, p. 72-88.

7. Centers for Disease Control and Prevention. 2017, Breastfeeding report card: progressing toward national breastfeeding goals United States 2016, *National Center for Chronic Disease Prevention and Health Promotion: Division of Nutrition, Physical Activity, and Obesity*, p. 1-8, https://www.cdc.gov/breastfeeding/data/reportcard.htm (November 25, 2017).

8. Centers for Disease Control and Prevention. 2013, 2014, National Immunization Survey (NIS): estimates of breastfeeding rates, CDC NIS, https://www.cdc.gov/breastfeeding/data/NIS_data/index.htm (November 25, 2017).

9. Der, G, Batty, GD, and Deary, IJ. 2006, Effect of breastfeeding on intelligence in children: prospective study, sibling pairs analysis, and meta-analysis, *BMJ (formerly British Medical* Journal), v. 333:7575, p. 945-950.

10. Hylander, MA, Strobino, DM, and Dhanireddy, R. 1998, Human milk feedings and infection among very low birth weight infants, *Pediatrics*, v. 102:38, p. e38.

11. Kaufman, FL. 1994, Managing the cleft lip and palate patient, *Pediatric Clinics of North America: Pediatric Oral Health*, v. 38, p. 1127-1147.

12. Lodge, CJ, Bowatte, G, Matheson, MC, and Dharmage, Sc. 2016, The role of breastfeeding in childhood otitis media, *Current Asthma & Allergy Reports*, vol. 9, p. 68.

13. Losee, JE and Kirschner, RE. "Nursing Care of the Patient with Cleft Lip and Palate." *Comprehensive Cleft Care*. McGraw Hill, New York, p. 149-170. Print.

14. Marazita, ML and Mooney, MP. 2004, Current concepts in the embryology and genetics of cleft lip and cleft palate, *Clinical Plastic Surgery*, v. 31:2, p. 125-140.

15. Masarei, A.G., Sell, D, Habel, A, Mars, M, Sommerlad, B.C., and Wade, A. 2007, The nature of feeding infants with unrepaired cleft lip and/or palate compared with healthy noncleft infants, *The Cleft Palate-Craniofacial Journal*, v. 44:3, p. 321-328.

16. Meier, P.P., Engstrom J.L., Janes, J.E., Jegier, B.J., and Lorea, F. 2012, Breast pump suction patterns that mimic the human infant during breastfeeding: Greater milk output in less time spent pumping for breast pump-dependent mothers with premature infants, *Journal of Perinatology*, v. 32, p. 103-110.

17. Oliver, R.G. and Jones, G. 1997, Neonatal feeding of infants born with cleft lip and/or palate: Parental perceptions of their experience in South Wales, *The Cleft Palate-Craniofacial Journal*, v. 34:6, p. 526-532.

18. Osterman M.J. and Martin, J.A. 2011, Epidural and spinal anesthesia use during labor: 27-state reporting area, *National Vital Statistics Report*, v. 59:5, p. 1-3, 16.

19. Paradise, J.L., Elster, B.A., and Tan L. 1994, Evidence in infants with cleft palate that breastmilk protects against otitis media, *Pediatrics*, v. 94, p. 853-860.

20. Parker, S.E., Mai, C.T., Canfield, M.A., Rickard, R., Wang, Y., Meyer, R.E., Anderson, P., Mason, C.A., Collins, J.S., Kirby, R.S., and Correa, A. 2010, for the National Birth Defects Prevention Network. Updated national birth prevalence estimates for selected birth defects in the United States, 2004—2006, *Birth Defects Research (Part A): Clinical and Molecular Teratology*, v. 88, p. 1008-1016.

21. REDCap, ITHS University of Washington. Study data were collected and managed using REDCap electronic data capture tools[1] hosted at the Institute of Translational Health Sciences. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

REDCap at ITHS is supported by the National Center For Advancing Translational Sciences of the National Institutes of Health under Award Number UL1 TR002319.

[1] Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81.

22. Reid, J., Kilpatrick, N., and Reilly, S. 2006, A prospective, longitudinal study of feeding skills in a cohort of babies with cleft condition, *The Cleft Palate-Craniofacial Journal*, vol. 43:6, p. 702-709.

23. Reilly, S., Reid, J., Skeat, J., Petrea, C., Mei, C., Bunik, M., and the Academy of Breastfeeding Medicine. 2013, ABM Clinical Protocol #17: Guidelines for breastfeeding infants with cleft lip, cleft palate, or cleft lip and palate, revised 2013, *Breastfeeding Medicine*, vol. 8:4, p. 349-353.

24. Ross, R.B. and Johnston, M.C. 1979, Cleft Lip and Palate. R. Kfieger Publishing, New York. Print.

25. Rubin, R. 1984, Maternal Identity and the Maternal Experience, Spinger Publishing, New York, p. 16.

26. Smedegaard, H.V., Marxen, D., Moes, J., Glassou, E., and Scientsan, C. 2008, Hospitalization, breast-milk feeding, and growth in infants with cleft palate and cleft lip and palate born in Denmark, v. 45:6, p. 628-632.

27. Vohr, B.R., Poindexter, B.B., Dusick, A.M., McKinley, L.T., Langer, J.C., Poole, W. K., and the National Institute of Child Health and Human Development National Research Network. 2007, Persistent beneficial effects of breast milk ingested in the neonatal intensive care unit on outcomes of extremely low birth weight infants at 30 months of age, *Pediatrics*, v. 120:4, p. e953-e959.

CURRICULUM VITAE