Scientific Review Committee

Protocol Template and Instructions

This template should be used for studies which do not involve new investigative drugs or devices which involve a funded randomized clinical trial and/or FDA approval. If your study will involve testing of an investigational new drug or device in human subjects, please contact Alison Oville (aoville@connecticutchildrens.org) in Clinical Trials.

This template is applicable to most studies, including observational studies, pre/post-intervention studies, case/control studies, biological sample collection, qualitative studies, cross-sectional studies, and studies that randomized into standard of care treatment.

The purpose of this protocol template is to assist you in addressing all aspects of study design. Not all of the questions listed below may apply to your specific study. Skip the ones that are not applicable.

Instructions and examples are listed in each section of the protocol in red. **Please delete them as you complete each section**.

The goal of a protocol is to provide enough detail that anyone can read your protocol and duplicate your study. If your protocol is written appropriately, you should be able to copy/paste into the background and methods section of a manuscript without having to add additional details.

Most protocols must be approved by the Scientific Review Committee before submission to the IRB. Studies that don't require SRC review are:

- Multi-centered studies where Connecticut Children's is a participating site, NOT the lead site.
- Non-human subjects research. **Determination of this status must come from the IRB.**
- Federally funded or other grant funded studies which have undergone scientific review during the grant review process. **If not federally funded, determination of this status must come from the SRC and IRB**.

If you believe your study qualifies for any of the above, contact the SRC for determination of waiver (src@connecticutchildrens.org). Please note that, while the majority of the above studies do not require SRC review, the IRB may request SRC review in some circumstances.

SRC PROTOCOL TEMPLATE

PROTOCOL TITLE: **The effect of body position on oropharyngeal swallow function in infants**

PROTOCOL VERSION DATE:

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Background/Introduction

Infants are typically fed in a cradled, upright position. With at-risk infants, feeding specialists may adopt a side-lying position to promote safe, quality, and neurodevelopmentally protective feeding (Park et al., 2018). Current literature to support this practice suggests that side-lying position improves physiologic stability during feeding as compared to the traditional cradled or upright position (Park et al., 2014; Clark et al., 2007). Side-lying position has several theoretical benefits based on various mechanisms including its similarity to the natural breast-feeding position, reduced hydrostatic pressure of the bottle when it is held horizontally rather than vertically above the infant, increased ease of coordinating suck-swallow-breath due to decreased flow rate, and reduced work of breathing, (Park et al., 2018; Shaker, 2012; Shaker, 2019; Mizuno et al., 2000). Another possible reason that side-lying position is beneficial is improved swallow function including decreased incidence of penetration or aspiration, which is the term for food or liquid entering the airway (Mills et al., 2020). Aspiration can have devastating effects on infants, particularly premature infants, including respiratory illnesses, need for increased respiratory support, inability to maintain nutrition orally, long term lung damage, and even death (de Benedictis et al., 2009; Gewolb & Vice, 2007; Jadcherla, 2019; Lefton-Greif et al., 2006; Mizuno et al., 2007; Serel Arslan et al., 2018; Sheikh et al., 2001; Taniguchi & Moyer, 1994). Side-lying position is often recommended by feeding specialists to reduce the risk for aspiration and improve other components of infant swallow function. However, there is no literature directly assessing airway protection during the swallow with the infant in the side-lying versus upright positions.

Modified Barium Swallow Studies (MBS) are considered gold standard evaluations of swallowing function and are used to determine the safest bottle-feeding plan for medically-complex infants (Arvedson et al., 2020; Balest et al., 2021; Han et al., 2020)). MBS performed on infants typically assess multiple parameters, including suck-swallow-breathe coordination and sequencing, pharyngeal residue, timing of swallow initiation, upper esophageal sphincter opening, and presence of penetration (material entering the airway but remaining above the vocal folds) or aspiration (material entering the airway and passing below the vocal folds into the trachea). These studies have traditionally been completed in the upright/cradled position, despite the use of side-lying position clinically. However, this practice is changing, as some clinicians use side-lying during MBS to improve swallow safety and therefore inform feeding recommendations. This study aims to investigate whether there are changes in swallow function of infants fed in side-lying vs upright position during MBS. MBS will be analyzed to assess infant swallow function in side-lying position compared with swallow function in upright position. The following swallow parameters will be analyzed comparatively by position: airway invasion as defined by penetration and aspiration; location of the bolus at the time of swallow initiation, and suck-swallow-breathe coordination.

Previous literature suggests that infants fed in side-lying position are better able to control bolus rate and direction of flow than when they are fed in an upright/cradled position (Girgin et al, 2018; Park et al, 2018; Mills, 2020); however, these studies use physiologic outcomes and do not actually confirm if this hypothesized benefit is true. Pilot data found that infants were better able to protect their airway during the pharyngeal swallow, as evidenced by reduced rates of penetration or aspiration. Penetration is defined as material entering the airway during feeding but remaining above the vocal folds, whereas aspiration denotes material passing below the vocal folds towards the lungs, as measured by the Penetration-Aspiration Scale.

Side-lying position is hypothesized to reduce flow rate of liquid from the oral cavity into the pharynx, allowing the infant increased time to initiate the swallow and protect the airway (Mills et al., 2020; Mizuno 2000; Raczynksa et al., 2019). Previous literature suggests that infants fed in side-lying position are better able to control bolus rate and direction of flow than when they are fed in an upright/cradled position, leading to swallow initiation with the bolus higher in the pharyngeal cavity.

Previous research suggests that infants fed in side-lying position demonstrate improved oxygenation, which may be due to the infants' ease of coordinating breathing and swallowing during feeding (Mizuno 2000; Park et al., 2018; Raczynksa et al., 2019) Suck-swallow-breathe coordination may be easier when fed in side-lying position because of the reduced gravitational pull of the liquid into the infant's mouth, and the increased ability to control the flow rate. Pilot data revealed that infants demonstrated fewer swallows per breath when fed in a side-lying position, which may indicate a more coordinated swallow-respiration sequence.

Pilot data revealed that airway invasion (penetration and aspiration) was statistically significantly reduced, location of the bolus at time of swallow initiation was statistically significantly higher, and number of swallows per breaths were statistically significantly lower when infants were fed in a side-lying position compared to an upright/cradled position (Smith et al. 2022). That pilot investigation validates the need for additional research to further define the mechanisms related to this improvement, and to determine how diagnosis and medical stability moderate these findings.

If findings support that side-lying position decreases aspiration risk, it updates the standard of care for feeding, especially for at-risk infants who are not able to undergo instrumental swallow testing. Side-lying is a no-cost strategy with the potential to enhance infant and caregiver quality of life through safe and developmentally appropriate nutritional intake. Conversely, if results indicate side-lying increases swallowing risk in certain populations, this is also significant and directs the standard of care for hospitals that routinely advise side-lying in the absence of instrumental swallow testing. This work informs best practices for clinical practitioners (e.g., SLP, RN, MD, etc.) and infant caregivers (i.e., parents) to minimize the risk of aspiration and its possible health consequences.

Research Question

The purpose of this study is to investigate changes in swallow function based on positioning during infant Modified Barium Swallow Studies (MBS). Although there are several theoretical benefits to side-lying position, and feeding specialists use side-lying as a strategy to decrease aspiration risk, there is no current literature instrumentally evaluating, through x-ray imaging of the swallow mechanism, infant swallow function in various positions. This study will prospectively examine infant MBS that are completed at least partially in both side-lying and upright position, and will compare specific parameters of the swallow in these two positions.

The research questions are: 1) does side-lying position decrease the incidence and severity of airway invasion during feeding? 2) does side-lying position impact the location of the bolus at the time of swallow initiation? 3) does side-lying position improve suck-swallow-breathe coordination?

Primary and Secondary Aims

Primary Aim: To determine if side-lying position improves oropharyngeal swallow function, as defined by airway protection, swallow initiation, and suck-swallow-breathe coordination, in at-risk infants (Mills et al., 2020; Park et al., 2018; Raczynksa et al., 2019; Smith et al., 2022)

Hypothesis #1: Infants will have decreased incidence and severity of airway invasion (penetration or aspiration) when fed in side-lying position as compared to when they are fed, with the same bottle and nipple, in upright position.

Hypothesis #2: Infants will demonstrate higher bolus location at the time of swallow initiation when fed in side-lying position as compared to when they are fed, with the same bottle and nipple, in upright position (Gosa et al., 2015; Mills et al., 2020; Mizuno et al., 2000; Raczynksa et al., 2019*)*

Hypothesis #3: Infants will demonstrate improved suck-swallow-breathe coordination when fed in side-lying position as compared to when they are fed, with the same bottle and nipple, in upright position (Mizuno 2000; Park et al., 2018; Raczynksa et al., 2018).

Secondary Aim: To determine if the effect of side-lying position is moderated by medical stability and/or medical diagnoses such as chronic lung disease or neurologic conditions. (Geddes & Sakalidis, 2015; Smith et al., 2022)

Outcome Definitions/Data Points Collected

Primary Outcomes:

Airway invasion outcome will be measured via the Penetration-Aspiration Scale (Rosenbek et al., 1996). The PAS is an 8-point scale that is a reliable measure of airway invasion in infant bottle-feeders (Gosa & Suiter, 2011; Martin-Harris et al., 2020). The highest observed PAS score will be reported for each swallowing clip.

Secondary Outcomes:

Swallow initiation outcome will be measured by indicating the location of the bolus head (i.e., base of tongue-BOT, vallecula-V, pyriform sinuses-P) at the onset of base of tongue propulsion (Gosa et al., 2015). Lowest location of bolus (presenting highest risk) will be recorded for each swallowing trial (of one infant, one bottle/nipple type, and one modality at either side-lying or cradled position) (Dharmarathna et al., 2021; Gosa et al., 2015; Lefton-Greif et al. 2018; Martin-Harris et al., 2020; Mills 2020).

Suck-swallow-breathe (SSwB) coordination outcome will be assessed using three ratio measures: between sucks to swallows, sucks to breaths, and swallows to breaths (Barlow, 2009; Lau, 2013; Sakalidis et al., 2013; Geddes & Sakalidis, 2015). Sucks per swallows generally represents sucking efficiency, indicating how many sucks are required to form a bolus, whereas swallows to breaths is more indicative of coordination of swallow-respiration (Fucile et al., 2012, Lagarde et al., 2019; Sakalidis et al., 2013). Optimal coordination is considered a 1:1:1 SSwB ratio (Lau , 2013; Lagarde et al., 2019; Palmer, 1993). The number of sucks (S), swallows (Sw), and breaths (B) were counted for each swallowing trial.

Other data collected:

Demographic information will also be collected on each infant, including gestational age at the time of birth and post-menstrual age at time of MBS completion. Post-menstrual age (PMA) indicates the time between the last day of menstruation to birth (gestational age), plus the

chronologic age (post-natal age) (American Academy of Pediatrics, 2004). PMA is used to standardized age measures related to neurodevelopmental outcomes such as sucking and swallowing development, and is consistently used in literature assessing swallowing function in bottle fed infants including those who have been born prematurely (Balst et al., 2021, Han et al. 2020; McGratten et al., 2020).

Medical diagnoses and co-morbidities will also be collected on each infant. These data will be used as covariates to determine if age and medical status moderate the effect of body position on the primary and secondary outcome measures.

Study Design

This study is a single-center, prospective, within-subjects design. Data will be collected from a single center (CT Children's) via convenience sampling (i.e., only infants already referred for an MBS based on clinical need). All participants will be assessed in both a side-lying and upright position. Participants will be randomly assigned to side-lying position first, or side-lying position second during their modified barium swallow study.

Target Population

The target population are infants between post-menstrual ages (PMA) of 38-56 weeks who are referred for a modified barium swallow study at Connecticut Children's Medical Center between December 2022 and December 2023. No infants will receive an MBS who are younger than 38 weeks PMA, per hospital protocol and standard of practice in the field (Arvedson et al, 2020). Infants may be included who were born term or prematurely. As described above, gestational age at birth and PMA at time of MBS will be collected as secondary data. Therefore, data will be able to be stratified between infants who were born prematurely (<38 weeks gestation) and those born at term (>38 weeks gestation).

Inclusion/Exclusion Criteria

Inclusion Criteria

Infants who meet the following criteria are eligible for enrollment:

1. The age of the infant at the time of the study must be between 38 to 56 weeks post-menstrual age (PMA) (American Academy of Pediatrics, 2004; Balest et al., 2021, Han et al. 2020; McGratten et al., 2020).
2. Infant has been referred for an MBS by their physician based on clinical need (suspected oropharyngeal dysphagia)
3. Only infants with confirmed pharyngeal dysphagia, as defined by at least one airway invasion event on their MBS, will be included in final data analysis

Exclusion Criteria

1. Infants who are deemed not medically stable enough to complete an MBS

2. Infants who are deemed unable to maintain a side-lying or upright position for at least 3 minutes
3. Infants who do not meet the inclusion criteria above

Sampling Method/Recruitment Process

Infants will be recruited for the study only after they have been referred by their physician for an MBS, based on clinical indications and/or suspected oropharyngeal dysphagia. No infant will receive an MBS solely for the purposes of this study. Parents of potential infant participants will be approached by the evaluating Speech-Language Pathologist who already has access to the medical charts and active medical orders for the evaluation and treatment of dysphagia for that infant. No advertisement will be conducted given the convenience sampling procedure of including only infants who have a clinical indication for the need for an MBS and who meet the inclusion criteria. Informed consent will be obtained from every participant.

Study Retention/Withdrawal

The study design only requires the participants to attend one research sessions, which is their MBS which is prescribed for clinical reasons and will be used to determine feeding plan. No additional research sessions will be required outside of this single MBS. This will not only improve recruitment compared to a multi-visit design, but also helps with attrition. If a participant chooses to withdrawal from the study, the images collected from the MBS will be stored within the EMR for clinical purposes, as is current practice at Connecticut Children's.

Study Procedures

Infants will be recruited from Connecticut Children's. Infant participants may be referred from inpatient units, outpatient feeding therapy and evaluations, aerodigestive clinic, and craniofacial clinic. Parents of eligible infants will be approached for participation in the study by the evaluating Speech-Language Pathologist. Informed consent will be obtained from the legal caregivers of every participating infant. The following research procedures will be conducted for each participant.

MBS Procedures

MBS will be completed in the current fluoroscopy suites within diagnostic imaging at Connecticut Children's. MBS will be completed by a speech-language pathologist (SLP) and pediatric radiologist, resident, or physician's assistant. All SLPs involved in data collection have specific training in infant MBS and have been signed off as competent per hospital protocol. MBS will be performed in accordance with current hospital protocols including the use of at least 30 fluoroscopy pulses per second and collimation determined by the treating radiologist. As per current standards, bottle feeding trials will be administered starting with thin liquids (VARIBAR® Thin Liquid barium sulfate powder mixed with sterile water per manufacturer instructions) via slow or standard flow of each infant's typical bottle system (Arvedson et al., 2020; Patel et al., 2016). Subsequent bolus presentations and compensatory interventions (e.g., change in liquid consistencies/viscosity, change in nipple flow rates, etc.) will be determined as clinically indicated based on the infant's response to the initial swallowing trial, per the

discretion of the evaluating SLP and radiologist (Arvedson et al., 2020; Fishbein et al., 2013; Patel et al., 2016; Sitton et al., 2011; Suterwala et al., 2017). Each trial should be assessed for at least 5-6 swallows to maintain consistency across trials. SLP may decide to turn off fluoroscopy and allow the infant to continue swallowing to assess for fatigue as long as fluoroscopy is turned back on, and infant is assessed for a total of 6 swallows with that consistency, modality, and liquid viscosity in each position.

Positioning Procedures

Order of body positioning during swallowing trials will be determined randomly and assigned via research packets, to which the SLP and radiologist will be blinded until entering the room to set up for the MBS. Once positioning order has been revealed, the SLP and radiology technicians will set up the room to accommodate the first position. For upright position first, the fluoroscopy machine will be in standard upright positioning for an MBS with the infant in upright position of at least 60 degrees in a Tumble Forms seat (Patterson Medical/Performance Health). For side-lying position first, the fluoroscopy table will be placed horizontally with a slight elevation of between 10-15 degrees. Infants will be assessed in each position for no longer than 1.5 minutes of fluoroscopy time, to ensure a maximum of 2-3 minutes total of radiation exposure (no more than 1.5 minutes in each position), per current standard procedure at CT Children's. After the allotted time in the first position, infants will be repositioned by the SLP and radiology technicians into the alternative position (either upright or side-lying) for the remainder of the study. The performing clinician will assess the infant in the second position with at least 2 of the same bottle, nipple, and/or liquid viscosity combinations that were offered in the first position to allow for direct comparison of swallow function in each position for each infant.

It is important to note that MBS performed at Connecticut Children's often employ the use of both side-lying and upright positions during a single MBS for bottle-fed infants. Additionally, changes in bottles, bottle flow rate, and/or changes in liquid viscosity are components that are changed within studies. The single, experimental component of this study is the randomization of the order of position. No other changes will be made to standard of care for MBS completion (ie no changes to type of bottle, liquid viscosities, or radiation exposure compared to current standard of care).

Data Collection

Video recordings of MBS images will be collected by the evaluating SLP and/or PIs for analysis after completion. Demographic information will be collected by the treating SLP and documented on the study participant form. Study participant forms (see attached) do not include identifying information such as names or MRNs. This de-identified information will be transferred to the PIs and research team via Filelocker or other secure information sharing platform. Data will be stored at Connecticut Children's in the locked SLP office. Data shared via Filelocker will be accessed by the PIs and co-researchers at Southern Connecticut State

University (SCSU) in the locked Voice and Swallow Physiology Lab (VSPL). The SCSU VSPL is secured on the 2nd floor of the Health and Human Services Building and is HIPPA compliant.

Swallow function will be analyzed only for comparative trials; that is, where the infant was imaged with the same bottle, nipple, and liquid viscosity in both upright and side-lying position. This approach enhances reliability by reducing the impact of extraneous variables such as bottle, nipple, and viscosity on any observed differences in outcome measures. MBS video clips for upright and side-lying position will be analyzed via eUnity™ SMIL PACS Viewer (Copyright © 2020 Client Outlook) or QuickTime player (Apple Inc.) such that frame-by-frame analysis is possible.

Airway invasion will be measured using the Penetration-Aspiration scale (PAS) (Rosenbek et al., 1996). The PAS is an 8-point scale that is a reliable measure of airway invasion in infant bottle-feeders (Gosa & Suiter, 2011; Martin-Harris et al., 2020). PAS scores will be independently analyzed by a speech-language pathologist who did not perform the MBS and who is blinded to patient and examination information (i.e., MBS results and report). The highest observed PAS scores will be recorded for each swallowing clip. After independent analysis, scores will be compared to the performing SLP's scores. In cases where the scores differ, a third speech-language pathologist, who is blinded to patient and examination information, will review the images and discrepancies will be resolved by a consensus rating approach (Lefton-Grief, et al., 2018; McGratten et al., 2020). All SLPs involved in analysis have a minimum of three years' experience conducting infant MBS.

Two additional parameters of swallow function—bolus location at the time of swallow initiation and suck-swallow-breathe coordination—will be assessed with the intent to establish the mechanism (i.e., physiologic cause) of potential changes in airway invasion in side-lying position compared to upright/cradled position. Swallow initiation will be measured by indicating the location of the bolus head (i.e., base of tongue-BOT, vallecula-V, pyriform sinuses-P) at the onset of base of tongue propulsion (Gosa et al., 2015). Lowest location of bolus (presenting highest risk) will be recorded for each swallowing trial (of one infant, one bottle/nipple type, and one modality at either side-lying or cradled position) (Gosa et al., 2015). As with PAS scores, consensus scoring will be implemented for bolus location at the time of swallow initiation.

Suck-swallow-breathe (SSwB) coordination will be assessed using three ratio measures: between sucks to swallows, sucks to breaths, and swallows to breaths (Barlow, 2009; Lau, 2013; Sakalidis et al., 2013; Geddes & Sakalidis, 2015). Sucks per swallows generally represents sucking efficiency, indicating how many sucks are required to form a bolus, whereas swallows to breaths is more indicative of coordination of swallow-respiration (Fucile et al., 2012, Legarde et al., 2019; Sakalidis et al., 2013). Optimal coordination is considered a 1:1:1 SSwB ratio (Lau , 2013; Legarde et al., 2019; Palmer, 1993). The number of sucks (S), swallows (Sw), and breaths (B) will be counted for each swallowing trial. Visible opening of the larynx was used as a proxy measurement for a breath. Counting started after the first identifiable breath (laryngeal opening) in each swallowing trial recording, to accurately measure the full nutritive sucking burst. Suck-swallow-breathe ratios were determined by dividing the number of sucks to swallows, number of swallows to breaths, and number of sucks relative to breaths (Sakalidis et al., 2013).

Sample Size Justification

The sample size for this study will be 40 infants. An a priori power analysis was conducted using G-Power to evaluate the sample size required to detect a statistically significant difference, based on pilot data. The analysis indicated that a sample size of 8 would provide a power of .9 with a large effect size (>.5). However, given plan for additional analysis including medical diagnosis as a covariate, sample size was multiplied by five to accommodate subgroups of at least 8 infants per medical diagnosis category (respiratory, neurologic, GI, cardiac, and craniofacial).

Feasibility, Accrual, and Expected Duration of Accrual

SLPs at Connecticut Children's conduct at least 2 MBS (<3 months age) per week, which totals approximately 4-8 per month. It is estimated that approximately 20% of infants will not meet the inclusion criteria or caregivers will decline to participate. Therefore, it is anticipated that it will take a minimum of 10-12 months to accrue the goal sample size (n=40).

Study Limitations

Given that the data collection will come from clinically indicated studies, there are some limitations to the implementation of experimental design. Clinicians will select bottle, nipple, and liquid viscosity trials based on clinical need of the infants. Therefore, there will be variation in the trials offered across infants. However, given that this is a within subjects design comparing each infant to themselves across positioning, this limitation should not impact effect dramatically.

Another limitation is the use of laryngeal opening as a proxy for breath measurement. While the addition of equipment such as respiratory inductance plethysmography would add to the validity of the suck-swallow-breathe coordination measurements, we are limited by the equipment, space, and time availability of the current fluoroscopy suits.

Data Analysis

Statistical analysis will compare matched-pairs of MBS swallowing clips (same infant, same bottle/nipple, same liquid viscosity, in upright/cradled and side-lying positions) using cumulative link mixed models (clmm) with the clmm function from the "ordinal" package in R (Christensen, 2019). Location of bolus at time of swallow initiation will also be compared using a clmm for ordinal data given that location of bolus head represents level of risk of airway invasion. In all models, participant ID will be included as a random effect. For each set of model comparisons, a null model (with no fixed predictor) will be compared using a likelihood ratio test—against one where the infant's position (upright vs. side-lying) is included as a predictor. To measure the effect of position on PAS, the ordinal PAS level (1, 2, or 3) is the outcome variable, and to measure the effect of position on bolus location, the ordinal bolus location (1, 2, or 3) is the outcome variable.

The suck-swallow-breathe ratios will be compared using dependent measures t-tests. Additional analysis of the relationship between position and swallow-breathe ratio will be conducted using linear mixed-effects models using the "lmer" function from the lme4 package in R (Bates et al., 2015). In each model, swallow-breathe ratio is the outcome variable and participant ID is included as a random effect.

Organization/Roles and Responsibilities

Sara Burnham (sburnham@connecticutchildrens.org) is the Primary Investigator for this study and as such will be the primary contact person for the Scientific Review Committee and Institutional Review Board. She is a Speech-Language Pathologist at CT Children's and will be responsible for identifying participants, filling out study packets, uncovering randomized position order, implementing positioning changes during the MBS, analyzing the MBS (per current practice for clinical purposes), participate in consensus coding, and analyze data in conjunction with Dr.Smith and Dr.Mabry.

Dr.Kelly Mabry (Kmabry@connecticutchildrens.org) is a co-investigator. She is a Speech-Language Pathologist at CT Children's as well as a faculty member at Southern Connecticut State University. Dr.Mabry will support co-investigators with identifying participants, filling out study packets, uncovering randomized position order, and oversee data collection and analysis in conjunction with Dr.Smith and Sara Burnham.

Dr. Julian Smith (smithj181@southernct.edu) is a co-investigator. Dr. Smith is a faculty member at Southern Connecticut State University and does not have a direct affiliation with Connecticut Children's. Dr. Smith will oversee data collection and analysis in conjunction with Dr. Mabry and Sara Burnham.

Lauren Varholak (lvarholak@connecticutchildrens.org) is a co-investigator. She is a Speech-Language Pathologist at CT Children's and will be responsible for identifying participants, filling out study packets, uncovering randomized position order, implementing positioning changes during the MBS, analyzing the MBS (per current practice for clinical purposes), and will participate in consensus coding.

Katie McLoughlin (kmcloughlin@connecticutchildrens.org) is a co-investigator. She is a Speech-Language Pathologist at CT Children's and will be responsible for identifying participants, filling out study packets, uncovering randomized position order, implementing positioning changes during the MBS, analyzing the MBS (per current practice for clinical purposes), and will participate in consensus coding.

Use of Study Results

Results of this study will be submitted for presentation and national conferences such as the Society for Ear, Nose, Throat Advancement in Children (SENTAC) and for publication in a peer-reviewed journal.

Study Budget

The cost of this study is limited to the cost of obtaining recorded modified barium swallow studies. Personnel listed above will be conducting MBS as part of their current clinical duties.

References Cited

American Academy of Pediatrics. (2004). Age Terminology During the Perinatal Period. *Pediatrics¸*114(5): 1362-1364.

Arvedson JC, Brodsky L, Lefton-Greif MA. (2020). Pediatric Swallowing and Feeding: Assessment and Management. Third edition. Plural Publishing

Balest, A.L., Mahoney, A.S., Shaffer, A.D., White, K.E., Theiss, R., & Dohar, J. (2021). Infant aspiration and associated signs on clinical feeding evaluation. *International Journal of Pediatric Otorhynolaryngology, 149.* https://doi.org/10.1016/j.ijporl.2021.110856

Barlow, S.M. (2009). Oral and respiratory control for preterm feeding. *Curr Opin Otolaryngol Head Neck Surg*, 17(3), 179-186.

Clark, L., Kennedy, G., Pring, T., & Hird, M. (2007). Improving bottle feeding in preterm infants: investigating the elevated side-lying position. *Infant,* 3(4), 154-158.

Dawson, J.A., Myers, L.R., Moorhead, A., Jacobs, S.E., Ong, K. Salo, F. & Davis, P.G. (2013). A randomized trial of two techniques for bottle feeding preterm infants. *Journal of Paediatrics and Child Health*, *49*, 462-466. https://doi.org/10.1111/jpc.12208

De Benedictis, F.M., Carnielli, V.P., & De Benedictis, D. (2009). Aspiration lung disease. *Pediatric Clinics of North America, 56*(1), 173-190. https://doi.org/10.1016/j.pcl.2008.10.013Dharmarathna, I., Miles, A., & Allen, J. (2021). Predicting penetration-aspiration through quantitative swallow measures of children: a videofluoroscopic study. *European Archives of Oto-Rhino-Laryngology*, 278, 1907-1916.

Fishbein, M., Flock, S. & Benton, K. (2013). Self-Assessment of Pediatric Feeding Therapists in the State of Illinois. *Perspectives on Swallowing and Swallowing Disorders*, 22(4), 129-141.

Fucile, S., McFarland, D.H., Gisel, E.G., & Lau, C. (2012). Oral and nonoral sensorimotor interventions facilitate suck-swallow-respiration functions and their coordination in preterm infants. *Early Human Development*, 88(6), 345-350.

Geddes D.T., Sakalidis V.S. (2015). Breastfeeding: how do they do it? Infant sucking, swallowing and breathing. *Infant*, 11(5): 146-50.

Gewolb, I.H. & Vice, F.L. (2007). Abnormalities in the coordination of respiration and swallow in preterm infants with bronchopulmonary dysplasia. *Developmental Medicine and Child Neurology, 48*(7). https://doi.org/10.1111/j.14698749.2006.tb01321.x

Girgin, B.A., Gozen, D., & Karatekin, G. (2018). Effects of two different feeding positions on physiological characteristics and feeding performance of preterm infants: A randomized controlled trial. *Journal for Specialists in Pediatric Nursing, 22.* https://doi.org/10.1111/jspn.12214

Gosa, M.M., & Suiter, D.M. (2011). *Reliability of the penetration-aspiration scale for use with pediatric populations* [PowerPoint slides]. ASHA Convention presentation.

Gosa, M.M., Suiter, D.M. & Kahane, J.C. (2015). Reliability for identification of a select set of temporal and physiologic features of infant swallows. Dysphagia, 30, 365-372. https://doi.org/10.1007/s00455-015-9610-9

Han, C., Shin, J., & Jeon, G.W. (2020). Development of swallowing function in infants with oral feeding difficulties. *International Journal of Pediatrics* vol. 2020, Article ID 5437376 https://doi.org/10.1155/2020/5437376

Jadcherla, S.R. (2019). Challenges to eating, swallowing, and aerodigestive functions in infants:A burning platform that needs attention! *The Journal of Pediatrics*, 211. https://doi.org/10.1016/j.jpeds.2019.05.025

Lagarde, M.L.J., van Alfen, N., de Groot, S.A.F., Geurts, A.C.H., & van den Engel-Hoek, L. (2019). Adaptive capacity of 2- to 5-month-old infants to the flow, shape, and flexibility of different teats during bottle feeding: a cross-sectional study. *BMC Pediatrics*, 19, 477. https://doi.org/10.1186/s12887-019-1859-y

Lau, C. (2013). Is there an advantage for preterm infants to feed orally in an upright or sidelying position? *Journal of Neonatal Nursing*, *19*(1):28–32. https://doi.org/10.1016/j.jnn.2012.03.013

Lefton-Greif, M.A., Carroll, J.L., & Loughlin, G.M. (2006). Long-term follow-up of oropharyngeal dysphagia in children without apparent risk factors. *Pediatric Pulmonology, 41*(11). https://doi.org//10.1002/ppul.20488

Lefton-Greif, M.A., McGrattan, K.E., Carson, K.A., Pinto, J.M., Wright, J.M., & Martin-Harris, B., (2018). First steps towards development of an instrument for the reproducible quantification or oropharyngeal swallow physiology in bottle-fed children. Dysphagia, 33(1), 76-82. https://doi.org/10.1007/s00455-017-9834-y

Martin-Harris, B., Canon, C.L., Shaw Bonilha, H., Murray, J., Davidson, K., Lefton-Greif, M.A., (2020). Best Practices in Modified Barium Swallow Studies. *American Journal of Speech-Language Pathology*, 29 (2S), 1078-1093.

McGratten, K.E., McGhee, H.C., McKelvey, K.L., Clemmens C.S., Hill, E.G., DeToma, A., Hill, J.G., Simmons, C.E., Martin-Harris, B. (2020). Capturing infant swallow impairment on videofluoroscopy: timing matters. *Pediatric Radiology, 50*, 199-206. https://doi.org/10.1007/s00247-019-04527-w

Mills, N., Keesing, M., Geddes, D., & Mirjalili, S.A. (2020). Flexible Endoscopic Evaluation of Swallowing in Breastfeeding Infants With Laryngomalacia: Observed Clinical and Endoscopic Changes with Alteration of Infant Positioning at the Breast. *Annals of Otology, Rhinology & Laryngology*, 130(7), 653-655.

Mizuno, K., Inoue, M., & Takeuchi, T. (2000). The effects of body positioning on sucking behavior in sick neonates. *European Journal of Pediatrics*, *159*(11):827-831. https://doi.org/10.1007/pl00008347

Mizuno, K., Nishida, Y., Taki, M., Hibino, S., Murase, M., Sakurai, M., & Itabashi, K. (2007). Infants with bronchopulmonary dysplasia suckle with weak pressures to maintain breathing during feeding. *Pediatrics, 120*(4), e1035–e1042. https://doi.org/10.1542/peds.2006-3567

Palmer, J.B., Kuhlemeier, K.V., Tippett, D.C., & Lynch, C. (1993). A protocol for the videofluorographic swallow study. *Dysphagia,* 8: 209-214.

Park, J., Thoyre, S., Knafl, G., Hodges, E., & Niz, W. (2014). Efficacy of semielevated sidelying position during bottle-feeding of very preterm infants: A pilot study. *The Journal of Perinatal and Neonatal Nursing, 28*(1):69–79. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/24476654

Park, J., Pados, B.F., & Thoyre, S. (2018). Systematic review: What is the evidence for the side-lying positon for feeding preterm infants? *Advances in Neonatal Care, 18*(4): 285 -294.

Rosenbek, J.C., Robbins, J.A., Roecker, E.B., Coyle, M.A., Wood, J.L. (1996). Apenetration aspiration scale. *Dysphagia, 11,* 93–98.https://doi.org/10.1007/BF00417897

Raczyńska, A. & Gulczyńska, E. (2019). The impact of positioning on bottle-feeding in preterm infants (≤ 34 GA). A comparative study of the semi-elevated and the side-lying position a pilot study. *Developmental Period Medicine*, *23*(2).

Sakalidis, V., Kent, J.C., Garbin, C.P., Hepworth, A.R., Hartmann, P.E., & Geddes, D.T. (2013). Longitudinal Changes in Suck-Swallow-Breathe, Oxygen Saturation, and Heart Rate Patterns in Term Breastfeeding Infants. *Journal of Human Lactation,* 29(2).

Serel Arslan, S., Demir, N., & Karaduman, A.A. (2018). Both pharyngeal and esophageal phases of swallowing are associated with recurrent pneumonia in pediatric patients. *The Clinical Respiratory Journal*, *12*, 767-771. https://doi.org/10.1111/crj.12592

Shaker, C. (2012, July 5). Problem Solving: Benefits of sidelying position for infants [blogpost]. Retrieved from https://shaker4swallowingandfeeding.com/2012/07/05/qa-time-sidelying-position-technique/

Shaker, C. (2019, January 5). Problem Solving: Benefits of sidelying position for infants and maintaining readiness for safe return to PO feeding [blog post]. Retrieved from https://shaker4swallowingandfeeding.com/2019/01/05/problem -solving-benefits of sidelying-for-infants-and-maintaining-readiness-for-safe-return-to -po-feeding/

Sheikh, S., Allen, E., Shell, R., Hruschak, J., Iram, D., Castile, R., & McCoy, K. (2001). Chronic aspiration without gastroesophageal reflux as a cause of chronic respiratory symptoms in neurologically normal infants. *CHEST, 120*(4). http://doi/org//10.1378/chest.120.4.1190

Smith, J.B., Kamarunas, E., & O'Donoghue, C.R. (2022). Side-lying position to reduce aspiration in at-risk infants? A case study analysis (Poster). 30th Annual Meeting of Dysphagia Research Society, San Juan, Puerto Rico.

Taniguchi MH, Moyer RS. Assessment of Risk Factors for Pneumonia in Dysphagic Children: Significance of Videofluoroscopic Swallowing Evaluation. Developmental Medicine & Child Neurology. 1994;36(6):495-502. doi:10.1111/j.1469-8749.1994.tb11879.x

Thoyre, S. M., Holditch-Davis, D., Schwartz, T. A., Melendez Roman, C. R., & Nix, W. (2012). Coregulated approach to feeding preterm infants with lung disease: effects during feeding. *Nursing research*, *61*(4), 242–251. https://doi.org/10.1097/NNR.0b013e31824b02ad

Weir, K.A., McMahon, S., Taylor, S., & Chang, A.B. (2011). Oropharyngeal aspiration and silent aspiration in children. *Chest, 140*(3), 5890597. https://doi.org/10.1016/01655876(94)90009-4

Appendices

Appendix A.

Participant Check List

Participant Number: _____

Parental Consent obtained: _____ Yes _____ No

Infant MRN: _____

Age of infant: _____ weeks PMA

Infant has diagnosis of cleft palate: ____ Yes ____ No

Infant has additional diagnoses of: _____
_____
_____

Study completed in both upright and elevated side-lying position: ____ Yes ____ No

Which position completed first (circle one)? Upright Side-lying

Trials offered (bottle, nipple/flow, consistency) and results/notes:

Upright position:

Side-lying position:

Other:

Total fluoroscopy time: _____ minutes
Total dose: _____

Appendix B.

Participant Enrollment Sheet

Participant ID	Date of Study	Age of Infant	Aspiration in Upright position (yes/no)	Aspiration in Side-lying position
#101	1/17/22	42 weeks	Yes	No