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Comparison of Breast Pump Suction Patterns in Achievement of Coming to Volume in Breast Pump-Dependent Mothers of Critically Ill Infants

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Protocol

1. **Project Title**: Comparison of Breast Pump Suction Patterns in Achievement of Coming to Volume in Breast Pump-Dependent Mothers of Critically Ill Infants

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3. **Abstract:**

Although compelling evidence exists that high doses of mother's own breast milk (mother's own milk; MOM) improves infant health, breast pump dependent (need to use a breast pump to obtain milk for infants too ill or preterm to breastfeed) mothers of critically ill infants often provide insufficient amounts of MOM to support these benefits. Insufficient MOM has its origins during the first 14 days postpartum, a critical window that includes secretory activation (SA; milk coming in; lactogenesis II) and the achievement of coming to volume (CTV; providing ≥ 500 mLs/day of MOM by day 14 postpartum). For all lactating mothers, SA must be achieved for lactation to continue, and achievement of CTV predicts provision of MOM through to neonatal intensive care unit (NICU) discharge in preterm very low birthweight (VLBW; <1500 g birthweight) infants. For this study, we posit that alternate breast pump suction patterns (BPSP; suction rate, intensity, and rhythm) may facilitate achievement of CTV in mothers who have achieved SA, but whose daily pumped MOM volumes indicate a high risk of not achieving CTV. Therefore, the overall objective of this study is to compare the clinical effectiveness of three different breast pump suction patterns on lactation outcomes, including achievement of SA, among pump dependent mothers of critically ill infants who demonstrate faltering lactation after achievement of SA. At 6-8 days postpartum, 90 pump dependent mothers of critically ill infants who have achieved SA, but demonstrate faltering lactation (<350 mLs/day pumped MOM volume), will be randomized to use one of three different BPSPs with two groups having alternative BPSPs and one group using the current practice standard for 7 days. Study outcomes will include the following; (1) pumped milk volume, (2) secondary lactation outcomes (whether or not mothers achieve CTV by day 14-15 postpartum, maintenance of secretory activation, MOM removal efficiency, and lactation duration); (3) maternal perceptions of comfort, effectiveness, efficiency, and convenience of the BPSPs, and (4) proportion of feedings consisting of MOM consumed by infants. Two exploratory aims will explore potential benefits of the 3 BPSPs on lactation outcomes of mothers with co-morbidities known to negatively affect the above-mentioned lactation outcomes and whether mothers at risk of suboptimal lactation who use an alternate BPSP achieve the same lactation outcomes as do mothers who do not demonstrate faltering lactation.

4. **Background**

Consumption of High Doses of MOM Reduces Potentially-Preventable Complications: A key approach to reduce complications in critically ill infants is ensuring they receive high doses of their mother's own breast milk (mother's own milk; MOM) until neonatal intensive care unit (NICU) discharge. Research repeatedly shows infants benefit immensely from consumption of high doses of MOM including decreased risk of short and long-term morbidities such as late onset sepsis,[1] retinopathy of prematurity,[2] neurodevelopmental delays,[3,4] bronchopulmonary dysplasia,[5] feeding intolerance,[6] and NEC.[7-9] MOM also decreases length of hospitalization as well as risk of illness, and re-hospitalization after discharge from the NICU.[1] Reducing complications, shortens hospital stays, and decreases short and long-term monetary costs associated with developmental delays, rehospitalization, and special needs. Benefits of MOM are dose dependent with infants consuming the most MOM receiving the most protection against complications.[1,10]

The Importance of the First 14 Days Postpartum for Breast Pump-Dependent Mothers of Critically Ill Infants: The first 14 days postpartum is a critical window for all lactating mothers because the mammary gland undergoes multiple "once-in-a-lifetime" biologic changes that are necessary for continued lactation, with removed MOM volume increasing from 15 mLs on day 1 postpartum to 500-600 mLs by day 5-6 postpartum.

However, mothers of critically ill infants in the NICU have multiple barriers to achievement of these biologic processes, including complete breast pump-dependency, meaning that the pump rather than the infant removes MOM and regulates continued lactation. Thus, these mothers are often unable to provide adequate MOM volume for infant feedings, compromising infant health. In particular, lack of achievement of CTV is the primary predictor of no MOM feeding at NICU discharge, and the window between achievement of SA (on average day 5.6 postpartum in breast pump-dependent mothers of preterm infants) and achievement of CTV on day 14-15 postpartum represents a short, but critical window for intervention in this population. Although breast pump-dependency is not modifiable, the type of breast pump, BPSPs, and mothers' use of the pump are modifiable factors that can potentially improve the achievement of CTV and subsequent longer-term lactation outcomes. In particular, during the transition from the endocrine (SA) to autocrine control of lactation, frequent and effective/efficient MOM removal is key to optimizing prolactin release from the brain, as well as leveraging the multiple autocrine and paracrine mechanisms that control continued MOM synthesis and release. Thus, modification of BPSPs that may optimize the effectiveness and efficiency of MOM removal between achievement of SA and CTV represents a promising "next step" intervention in this at-risk population.

The Role of Alternate BPSPs. Because critically ill infants admitted to the NICU are physiologically unable to fully feed directly at the breast, mothers are completely breast pump-dependent, meaning that they must use a breast pump to obtain MOM for their infant. Furthermore, in completely breast pump-dependent mothers, the pump rather than the infant regulates lactation processes, including suckling-induced prolactin release and the autocrine-paracrine mechanisms of "supply and demand". Thus, the pump must do more than just "get the MOM out" if lactation is to continue via these endocrine and autocrine mechanisms. Central to this concept is that the BPSP should mimic the healthy term infant during breastfeeding to the extent possible so that breast pump-dependent mothers receive mammary signaling that optimizes MOM synthesis and release. Previous studies reveal that the human infant uses species-specific sucking patterns during the early postpartum period as MOM volume is established. A member of this study team (PPM) partnered with Medela in 2008-2012 to create a BPSP that mimicked the human infant during the initiation of lactation. An RCT of 105 mothers demonstrated that the initiation BPSP resulted in significantly greater cumulative MOM volume during the first 14 days, and was significantly more efficient in MOM removal, saving important minutes for breast pump-dependent mothers.[11] This initiation BPSP is now embedded in Medela pumps throughout the world for use in the maternity setting, with instructions to use this BPSP (Plus) until the achievement of SA, then to switch to a Symphony plus 2-phase pattern which is a "one size fits all" approach to MOM removal.

BPSPs 1 and 2. The current study posits that two alternative BPSPs may be more effective in increasing pumped milk volume and thus achievement of CTV in breast pump-dependent mothers by offering alternatives to the "one size fits all" approach of using the standard care Symphony Plus BPSP after achievement of SA. Eligible mothers will have demonstrated faltering lactation (<350 mLs/day pumped MOM on postpartum day 6-8) after achievement of SA. Both BPSP 1 (slower rate with a long hold time and higher starting vacuum pressure) and BPSP 2 (faster rate with longer hold time during peak vacuum pressures) have been trialed in mothers of preterm infants, but not during this early postpartum time period nor with mothers who experience faltering lactation. Although different in the manner in which suction is applied and maintained during each pump cycle, both BPSPs have greater area under the suction curve (accomplished via modifications in suction pressure and duration) than does the standard Symphony Plus BPSP. Theoretically, these BPSPs afford "more time" per cycle for MOM removal, and may optimize endocrine and autocrine regulation of lactation, increasing MOM synthesis. These outcomes are reflected in the specific aims. An additional interest is whether these alternative BPSPs may be especially effective and/or efficient in mothers with co-morbidities such as overweight and obesity, for whom the extra area under the suction curve may improve MOM removal. However, equally important is maternal perceptions of comfort and ease of use for both BPSPs, especially during the early postpartum period when the mammary tissues are more prone to discomfort with either breastfeeding or breast pump use.

5. Specific Aims:

The **primary purpose** of this study is to compare the clinical effectiveness of three different BPSPs [BPSP1, BPSP2, and Symphony Plus (Standard Care)] on lactation outcomes among pump dependent mothers of critically ill infants with faltering lactation.

Specific aims are as follows:

Aim 1: Compare the clinical effectiveness of 3 different BPSPs on pumped milk volume during Days 8-15 postpartum.

Aim 2: Compare lactation outcomes for the three groups, including 1) maintenance of SA through to postpartum day 14-15, 2) rate of increase in daily pumped MOM volume, 3) whether or not mothers achieve CTV by day 14-15 postpartum, 4) cumulative pumped MOM volume over days 1-7 and 8-15) MOM removal efficiency, and 5) lactation duration.

Aim 3: Compare maternal perceptions of comfort, effectiveness, efficiency, and convenience of the 3 BPSPs.

Aim 4: Compare infant outcomes for the including: 1) proportion of feedings consisting of MOM during the NICU hospitalization, 2) proportion discharged consuming any MOM, and 3) proportion receiving MOM at 3 and 6 months of life.

Exploratory Aim 1: Explore potential benefits of the 3 BPSP on lactation outcomes of mothers with co-morbidities known to negatively affect lactation outcomes (high BMI/obesity, diabetes, pregnancy induced hypertension).

Exploratory Aim 2: Explore whether mothers categorized as having faltering lactation on postpartum day 6-8 and who use BPSP1, BPSP2, or Symphony Plus BPSP (Standard Care) achieve the same lactation outcomes (Aims 1, 2, 4) as do mothers who do not demonstrate faltering lactation at postpartum day 6-8.

6. Research Plan:

This study will use a randomized control trial design with 3 arms to compare the clinical effectiveness of three different BPSPs on lactation outcomes among pump dependent mothers of critically ill infants who demonstrate faltering lactation on day 6-8 postpartum. Mothers identified as having faltering lactation will be randomly assigned to one of 3 groups; (1) BPSP1, (2) BPSP 2, and (3) Symphony Plus BPSP (Standard Care).

Sample and Setting:

Up to 274, racially and economically diverse mothers and infants(s) who have delivered a critically ill infant(s) admitted to the NICU will be sampled from the obstetrical unit at UFHealth Shands Hospital which is associated with a Level IV (72 bed) NICU.

Inclusion criteria are: 1) $\geq$ 18 years of age, 2) delivered infant(s) of any GA admitted to the NICU including mom of multiples, 3) intent to provide exclusive MOM to their infants for the first 14 days, 4) expected to be breast pump -dependent for at least 14 days, and 5) English speaking.

Exclusion criteria are: 1) breast reduction or augmentation, 2) infant not expected to survive, 3) medications or maternal conditions incompatible with providing MOM for a NICU infant, and (4) resides over 60 miles from UFHealth.

The NICU at UF Shands admits infants that are racially diverse regardless of private or Medicaid insurance coverage. All mom that meets the above criteria would be eligible for enrollment. Informed consent will be obtained by mothers in their postpartum hospital room or in the NICU while visiting their infant prior to 48 hours postpartum. The informed consent includes mother's permission to access their infant's chart to collect information up until infant's discharge. The infant has no study interventions. In the rare instance that an infant breastfeeds, intake will be determined through test weighting (infant weight pre and post breastfeeding). Prior to the mother's hospital discharge, she will be provided an empty payment card where participants will receive compensation, by adding payments for completing study events, listed below. After enrollment, a 2-minute maternal interview will be used to collect information to determine pre-pregnancy BMI and other factors that might impact lactation success (Appendix B). Information will be collected related to pumping frequency and pumped milk volume prior to enrollment (Appendix I). All enrolled mothers will be provided breast pumping instructions to optimize their pumping behaviors prior to achievement of secretory activation. This 30-minute optimization session will be provided by a Research Nurse Coordinators, who is also an International Board-Certified Lactation Consultant (IBCLC). The instructions will be standardized using a score card, which provides prompts for education discussion and video links about pumping practices, breast and nipple assessment, breast shield sizing and comfort. (Appendix F). A daily sample of 0.3 mL of pumped MOM (if mother has pumped at least 5mL/day) will be tested for MOM sodium level as an indicator of secretory activation. At day 6-8 postpartum, mothers at high risk of suboptimal lactation will be identified and randomized to one of three BPSPs Mothers will be determined to be at risk if they have (1) achieved secretory activation (change from small volumes of colostrum to large volumes of more mature milk; determined by a milk sodium level < 20 mM) and (2) have a pumped milk volume < 350 mL/d. Mothers who are identified as being not at risk for suboptimal lactation (have achieved secretory activation and their pumped milk volume is $\geq$ 350mL/d) will not be randomized but will continue with standard care regarding BPSPs, and continue to have data regarding lactation collected. Mothers who do not reach SA, determined by a milk sodium level $\geq$ 20 mM, will be withdrawn from the study and referred to the UF Shands Lactation Team. All mothers that achieve SA, will be provided a second 30-minute standardized breast pumping optimization session with instructions by a Research Nurse Coordinator who is an IBCLCs at day 6-8 postpartum. Mothers will complete the Maternal Perceptions Survey (Appendix K/Part A only) before starting new pattern. If randomized, Moms will complete the Maternal Perception Survey (Part A/B) on Day 9-11. A score card, designed for mothers who have already achieved secretory activation, includes educational prompts and video links regarding milk volume, pumping behaviors, breast and nipple assessment, flange fit and comfort will be utilized. (Appendix G). Should a mother be unable to obtain transportation to the NICU, they will be provided transportation through Uber Health, provided they live within a 60-mile radius of UF Shands due to cost limitation of study.

Mothers will be provided a payment card for amount listed following completion of the listed study event(s).

1. All mothers enrolled: optimization pumping session with the study Research Nurse Coordinator IBCLC, completion of the first MAACL, maternal interview, and lactation experience questionnaire. ($25.00)
2. All mothers that achieve SA: Following completion of the second pumping optimization session with the study Research Nurse Coordinator IBCLC and completion of Maternal Perceptions Survey (Part A only) ($25.00)
3. All mothers that do not reach SA, will be withdrawn from the study and not eligible for further compensation.

4. Following completion of the second MAACL, lactation experiences survey, maternal perception survey (if randomized) and return of all "loaned" breast pumps ($50.00)

Total Compensation: Moms withdrawn at Week 1 (did not reach SA) $25.00.
All other moms (reaching SA) will receive up to ($100)

Sample Size Determination: With 30 dyads (mom and infants) will randomized, using the block method, to each intervention group (2 alternate, one standard care), assuming a = 0.02 (Type I error rate), two-sided; independent sample t-test comparison of means (adjusted for multiple comparison between 3 groups); equality of variance between groups with 30 mothers per group we will have 80% power to detect a difference of 300 ml (effect size of 0.84; sd=350.0) between the groups.

Randomization: Those mothers who have been identified as being at high risk for suboptimal lactation will be randomly assigned using Block randomization to use one of three different BPSPs [BPSP1, BPSP2, or Symphony Plus BPSP (Standard Care)] for 7 days.

Research Procedures and Analyses by Specific Aim.

Aim 1: *The primary aim of this study* is to compare the clinical effectiveness of 3 different BPSPs on pumped milk volume during Days 8-15 postpartum.

Mothers will have access to a hospital grade breast pump (Medela Symphony Plus) while hospitalized and when visiting their infant in the NICU (standard policy). Upon hospital discharge, all mothers will be provided the same hospital grade breast pump for home use. At 6-8 days postpartum, those mothers who undergo randomization, will be provided a hospital grade SMART pump (Medela, AG, Switzerland) as a substitute for the standard hospital breast pump. The SMART pump (the same breast pump used as standard care) has been adapted to electronically measure, record and store both pumping behaviors and weighed MOM volume (measured ± 0.1g; 1 g=1 mL). A card will be inserted into the SMART pump which will program the pump to either use BPSP1, BPSP 2, or Standard Plus). Mothers will be blinded to the BPSP used. Information is stored and the embedded computer chip is downloadable into a customized computer program (on a secure College of Nursing computer) at the termination of data collection. A SMART pump with the same randomized pattern will also be placed at their infant's bedside in the NICU to facilitate pumping in the NICU. Mothers will be provided a key tag to use prior to using the SMART pump to ensure only her pumping information is stored on the embedded computer chip. All mothers will be assisted to obtain a permanent breast pump for home use after study completion as per usual hospital care. Mothers that have been withdrawn from the study, at week 1, for not reaching SA, will be allowed to use the Medela Symphony Plus for 2-weeks, as needed.

Pumped milk volume will be measured daily using the following two method;

(1) Mothers will weigh each bottle of MOM using the SMART pump and this information will be recorded and stored (only those mothers who are randomized and only from day 8-15).

(2) All mothers will be provided pre-weighed and labeled vials to place their MOM following each expression per NICU policy and asked to bring all expressed MOM to the NICU. It is standard care in this NICU that all MOM brought to the NICU is weighed and the volume recorded in the infant's EMR (all mothers). Volume of pumped MOM will be determined by weight (1 mL = 1 gram). All MOM will be weighed by human milk technicians who have worked in this NICU's designated Human Milk Room since 2013, are not involved with direct care of either mother or infant and will be blinded to the group assignments. There are currently 7 human milk technicians covering the Human Milk Room 24/7 who

weigh and log each container of MOM delivered to the NICU. After MOM is weighed, it is available for infant consumption. Measurement of MOM volume (through weighing) will occur daily for 15 days. Although highly unlikely due to immaturity, if an infant breastfeeds, test weighing will be used to calculate volume of MOM consumed. Test weighing or weighing infants prior to and following breastfeeding, is an accurate method of determining intake during breastfeeding.[12] Prior to each breastfeeding session, infants will be weighed. Weight will include clothing, diaper, and blankets worn by the infant. Following breastfeeding, the infant will be weighed again, clad in the same clothing on a Baby Weigh scale (Medela, Inc., McHenry, Ill) to the nearest 0.2g. Differences between pre- and post-feeding weights will be recorded in the infant's EMR and added to the total volume the mother expressed on that day.

Aim 2: A second aim will compare lactation outcomes including 1) maintenance of secretory activation, 2) rate of increase in daily pumped MOM volume, 3) whether or not mothers reach coming to volume (CTV; pumped milk volume of $\geq$ 500 mL by day 14 postpartum). daily pumped MOM volume, 4) cumulative MOM volume over days 1-7 and 8-15) milk removal efficiency, and 5) lactation duration.

Maintenance of secretory activation. For all mothers enrolled in the study, maintenance of secretory activation will be defined as a daily MOM sodium level < 20mM.[13] A research assistant, blinded to group assignment, will collect 0.3 mL of MOM daily from vials of MOM brought to the NICU and place the sample onto the sensor of an ion selective electrode analyzer (HORIBA, Japan) which is a hand-held machine used for sodium and potassium analysis (see photo), has been validated for accurate analysis of human milk sodium and potassium levels, and will be calibrated prior to every analysis.[14] Although both sodium and potassium are secreted into milk via transcellular pathways, sodium but not potassium is also transferred from the maternal circulation via patent paracellular pathways. Thus, it has been suggested that a milk sodium to potassium ratio would standardize sodium level for individual women.[15] While no differences have been reported between the ability of sodium alone versus a Na:K ratio to predict pumped milk volume, we will also measure potassium levels.[16] (Appendix H) To ensure accuracy, individuals performing sodium analysis will be trained and evaluated prior to beginning analysis and quarterly. Our team is highly skilled in milk collection, processing and analysis.[13,17]

Rate of increase in daily pumped MOM volume, achievement of secretory activation (Yes/No), and cumulative MOM volume over days 1-7 and 8-15 postpartum. MOM volume will be measured as discussed in Aim 1 and each of the outcomes determined.

Milk removal efficiency. Efficiency of milk removal will be determined by mls of MOM pumped per minute of pumping (cumulative per day and cumulative over days 8-15). Minutes of pumping is measured and recorded on the SMART pump (Appendix M).

Lactation Duration. Number of days a mother lactates (either via breastfeeding or expressing MOM) during her infant's hospitalization and whether or not she is lactating at infant discharge will be collected. Mothers will be determined to have ceased lactation when they are no longer bringing MOM to the NICU, are not placing the infant to breast for nutritive or non-nutritive sucking, and states they are no longer lactating when questioned. If still lactating at their infant's NICU discharge, mothers in all groups will be questioned regarding their continued lactation through monthly text message hyperlinked surveys via the Qualtrics platform until their infant is 6 months of age or she has ceased lactation. If a mother ceased lactation within the past month, she will be asked the week within the past month she discontinued lactating (Appendix J).

Aim 3: Will compare maternal perceptions of comfort, effectiveness, efficiency, and convenience of the 3 different breast pump patterns.

Mother's perception regarding the comfort, rhythm, effectiveness, and ease of use of the three BPSPs will be assessed via a text message hyperlinked Qualtrics survey within 7 days of study completion. A reminder will be sent if no response in 7 days (Appendix K).

Aim 4: A fourth aim will compare proportion of feedings consisting of MOM consumed by infants between the 3 groups. Daily proportion of total feeds consisting of MOM consumed during the first 15 days and proportion of total feeds consisting of MOM consumed during the 24 hours prior to discharge will be recorded from the infant's EMR. Proportion of feeds that include MOM after discharge will be determined until the mother ceases lactation or the infant is 6 months old through monthly text message hyperlinked surveys through Qualtrics asking the total number of feeds in the past 24-hours that consisted of MOM (either direct breastfeeding or feeding expressed MOM).

Exploratory Aim 1: Will explore potential benefits of the three BPSPs on the lactation outcomes in Aim 1 and 2 of mothers with co-morbidities known to negatively affect lactation outcomes (high BMI/obesity, diabetes, pregnancy induced hypertension).[18] A subset of mothers diagnosed with high BMI/obesity, diabetes, and/or pregnancy induced hypertension will be classified as having 1, 2, or 3 risk factors known to negatively affect lactation outcomes. Potential benefits of the three BPSPs will be explored in this subset of mothers.

Exploratory Aim 2: Explore whether mothers identified as having faltering lactation who use an alternate BPSP (BPSP 1 or 2) achieve the same lactation success as mothers identified as not having faltering lactation (pumped MOM volume $\geq$ 350 mL/d by day 6-8). Lactation outcomes (see Aim 1 and 2) will be compared between mothers who were randomized to use either BPSP 1 or 2 and those mothers who were not randomized because they were not identified as having faltering lactation.

Confounding Variables. The following variables may affect pumped MOM volume in mothers of critically ill infants. While control of these variables within the study is impossible, we will carefully document these factors on all enrolled mothers to allow for inclusion in statistical analysis as adjustment variables. See **Table 1** for additional confounding variables.

Skin-to-skin care: Episodes and duration of skin-to-skin care (holding infants dressed in a diaper on their mother's bare chest) will be documented by bedside nurses and data collected from the infant's EMR. Skin to skin care has been associated with increased MOM production in observational studies,[19] yet the frequency or duration needed is not known, and skin-to-skin care may not be possible due to an infant's critical status.[20] Skin-to-skin care is encouraged in this NICU and nursing protocols are in place to provide support to all mothers. When stable and of appropriate maturity, infants too immature to orally feed are encouraged to suckle at an empty breast during skin-to-skin care and the number and duration of these episodes will be collected.

Lactation Support: Episodes of lactation support will be documented by lactation consultants in the infant's EMR. Although lactation support may improve breastfeeding success, limited data exists regarding the effect of lactation support in pump dependent mothers of critically ill infants.[21-23] There are 5 (3 FTE) lactation specialists providing services to mothers in the hospital and who evaluate all mothers prior to discharge and provide ongoing services to mothers whose infants remain in the NICU which is congruent with all mothers expressing MOM for infants in the NICU. Information regarding any lactation support mothers receive outside of UF Health will be determined through monthly surveys. If no response within 7 days, a one-time reminder will be sent (Appendix C; Appendix J).

Maternal Mood. Maternal mood affects breastfeeding success in healthy term infants and may impact lactation success in mothers of critically ill infants.[24,25] Prior to hospital discharge, and at 15 days postpartum, all mothers will be asked to complete the MAACL-R; a standardized instrument with well-documented psychometric properties that assesses mood states by using positive and negative mood state scales for Anxiety, Depression, Hostility, Positive Affect and Sensation Seeking. It consists of 132 adjectives at $\leq$ an 8th grade reading level,

takes approximately 3 minutes to complete. This test has been successfully used in lactating mothers of premature infants and in our previous studies.[26,27] While not designed to identify individuals with anxiety or depression needing medical or psychological intervention, each test will include a letter providing detailed instructions and phone numbers on how to obtain assistance through the crisis hotline or UF Department of Psychiatry if mothers feel anxious or depressed. Mothers will have standard access to social workers who work in NICU to support all mothers during their infants NICU stay.(Appendix D and E).

Table 1. Instruments

Variable	Measurement	Timing
Descriptive (1-2) below		
1. Maternal, prenatal and perinatal demographics	Age, Race/Ethnicity, parity, BMI, smoking, education, employment, maternal health, delivery mode, antenatal/birth complications, antenatal steroids, type of insurance delivery of more than 1 infant, date and time of birth. (App A; B)	Collected upon entry into study.
2. Infant demographics	Sex, gestational age, Apgars, weight, head circumference and length.	Collected upon enrollment, end of weeks 1 & 2 and at discharge.
Time to onset of secretory activation	Hours from delivery to a MOM sodium level of < 20mM (analyzed using an ion selective electrode analyzer, pumped MOM volume of 20 ml in 2 consecutive pumps; maternal report of breast fullness. (App H, App I)	Daily until onset of secretory activation
Maintenance of secretory activation	Defined as a MOM sodium level < 20 mM analyzed using an ion selective electrode analyzer (HORIBA, Japan). (App H)	Daily for 15 days
Volume of pumped MOM	Weight of pumped MOM. Total of each vial will be summed for a 24-hour total. (App L)	Daily for 15 days.
Volume of MOM if infant breastfeeds.	Test weighing - Difference in infant's weight before and after feeding as a measurement of MOM intake. (App L, App N)	Daily for 15 days.
Milk removal efficiency.	mL of MOM pumped per minute (App M)	Daily on days 8-15 postpartum
Lactation duration (1-2 below)		
1. Days mothers lactated during infant hospitalization.	Data extracted from electronic medical records and from maternal questioning.	Daily until infant discharge.
2. Weeks mothers lactated following infant discharge from the NICU.	Monthly maternal text message with hyperlinked surveys through Qualtrics. (App. J)	Monthly until lactation cessation or infant is 6 months of age.
Maternal perceptions of comfort, effectiveness, efficiency, and convenience	Hyperlinked surveys through Qualtrics (App K)	Complete Part A only (Day 6-8) Complete Part A & B (Day 9-12) if randomized to new pattern
Infant MOM consumption (1-3 below)		
1. Proportion of feeds consisting of MOM.	Data extracted from medical record or via test weighing of infants if they breastfeed. (App N)	Daily for 15 days
2. Proportion of feeds consisting of MOM at discharge	Data extracted from medical record or via test weighing of infants if they breastfeed. (App O)	For 24 hours prior to discharge
3. Duration of partial or exclusive MOM feedings after discharge	Monthly maternal text message with hyperlinked surveys through Qualtrics. (App J)	Monthly until lactation cessation or infant is 6 months of age.
Length of NICU hospital stay; infant nutritional, and health outcomes	Days infant remained hospitalized in the NICU, nutritional and health outcomes	From birth until discharge.
Covariates (1-6) below		
1. Demographic data	Maternal: Race/Ethnicity, delivery of > one infant, delivery mode, parity, BMI, co-morbidities. Infant: Gestational age at birth, birthweight, Apgar score. % of type of feeding consumed (MOM, donor human milk, formula). (App A, App N)	Upon entry into study and during the 15-day study period
2. Number of pumping sessions per day	# of times a mother pumps her breasts per day. (App L)	Daily for 15 days
3. Skin-to-skin care	Total minutes and episodes of skin-to-skin care.	Daily for 15 days.

4. Maternal mood	Results of 2 MAACL-R tests completed by mom. (App D)	Prior to her hospital discharge and at 15 days postpartum.
5. Lactation experience	(a) Feeding plan prior to delivery, previous experience with breastfeeding and/or pumping, lactation intent, home pump status (b) Lactation intent, lactation goals lactation consultations, galactagogues, mastitis diagnosis and treatment, use of hormonal birth control, home pump status (App C)	Before maternal hospital discharge (a) At end of study (b)

Table 2: Timeline of events over the 15-day study

Measure	0*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
• Consent, maternal interview		X-	-X													
• Pumping optimization		X-		-X			X-		-X							
• MOM NA/K Level		X-														-X
• Lactation risk assessment							X-		-X							
• Randomization							X-		-X							
• Determination of CTV																X
• Measures of pumped milk volume		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
• Measures of infant consumption of MOM		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
• Maternal perception survey (Part A)							X-		-X							
• Maternal perception survey (Part A/B)										X-		-X				
• MACCL			X-	-X												X
• Lactation experiences			X													X

* = day of birth

7. Possible Discomforts and Risks:

It is possible that mothers may find the alternate breast pump patterns uncomfortable. Should this happen, they will be asked if they would like to be withdrawn from the study and use their own breast pump consistent with standard care for all mothers pumping MOM for their infants in the NICU use.

8. Possible Benefits:

There is no direct benefit to mothers completing this study. Moms may possibly benefit from having a hospital grade breast pump to use at home for the 2-week study. Mothers who use alternate breast pump patterns may have improved lactation outcomes and their infants could receive higher doses of MOM.

9. Conflict of Interest:

There are no conflicts of interest.

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