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Shortening the Time Frame for Connecting Mothers of Infants Admitted to the NICU with Breast Pumps Using A Quality Improvement Approach

A. Study Purpose and Rationale Exclusive use of human milk for newborns is recommended by the American Academy of Pediatrics until 6 months of age, with continued breastfeeding alongside introduction of solid foods until 1 year of age (AAP 2012).

The benefits of breastfeeding include lower risk of asthma, type 2 diabetes, eczema, GI infections, ear and upper respiratory infections, inflammatory bowel disease, obesity, sudden infant death syndrome, and, most critically for the NICU population, reduced risk of necrotizing enterocolitis and late-onset sepsis, and improved outcomes in neurodevelopment (CDC 2018, AAP 2012).

Despite these well established benefits, in the United States, not all socioeconomic and ethnic/racial groups initiate breastfeeding at similar rates. Low income non-Hispanic black mothers have the lowest rates of initiation at 37% (AAP 2012). Given the potential stakes, researchers have investigated the reasons for potential disparities and found that "disparities in breastfeeding rates are also associated with variations in hospital routines, independent of the populations served. As such, it is clear that greater emphasis needs to be placed on improving and standardizing hospital-based practices" (AAP 2012).

Mothers of preterm infants face even greater difficulty in establishing and maintaining their milk supply, often because early delivery can lead to "inadequate mammary development and subsequent reduction in milk supply [...] because many VLBW infants are too immature to directly suck at the breast for several weeks of their NICU hospitalization, mothers rely on breast pumping or hand expression to produce milk, rather than direct breastfeeding; this can also lead to reduction in mother's own milk supply" (Parker and Patel, 2017).

When it comes to establishment of milk supply, timing is key. "Multiple studies have shown that early hand expression and/ or breast pumping are associated with increased mother's own milk production overtime. While studies have described increases in milk production when initiation occurs <6 hours after delivery, a recent study showed that initiation by mothers <1 hour after delivery led to greater milk volumes compared to mothers who initiated between 1 and 6 hours after delivery. Thus, it is recommended that mothers begin pumping and/or hand expressing their milk as soon as possible after delivery" (Parker and Patel, 2017).

At MSCHONY, the goal is generally accepted to be 4-6 hours post delivery. However, one of the most difficult features of implementing this goal is the availability of breast pumps. For mothers who are unable to initiate breastfeeding with their infant in the NICU, availability of a pump or knowledgeable lactation consultant who can explain hand expression is critically important. No

baseline data exists for how often the goal is met within our hospital, but anecdotal reports from doctors, nurses, and lactation consultants, would indicate that we do not always meet the goal. One physician reported a wait time of greater than 24 hours for a new mom in postpartum unit whose baby was in the NICU.

Therefore, there are likely gaps to fill in improving delivery of pumps to NICU mothers and a quality improvement project that aims to fulfill that goal will fill a critical need for the infants in our NICU.

B. Study Design This is a quality improvement project. Steps to successful project completion include development of an interdisciplinary team. Already several other staff including nursing, nurse management, and lactation consultant have shown interest in the project.

I will develop a set of aims, process measures, and a key driver diagram for the project initiation. Data collection will be initiated prior to implementing any change in order to obtain a sense of baseline data.

Determining interventions will occur in conjunction with the team who will help to implement changes. Input from nursing and lactation consultations will be critical in developing interventions.

Data will be assessed in an ongoing manner to determine the impact of programs for change. Run and control charts will both be used to determine success or need for adjustment of interventions.

C. Subject Selection Mothers in the CHONY postpartum unit whose babies are in the NICU with the desire and ability to breastfeed.

Mothers who are medically unable to breastfeed will be excluded from the study.

D. Statistical Procedures In order to demonstrate an improvement, I will need to provide pre and post implementation data. I estimate the baseline adherence to the 4 hour recommendation to be around 30%. The goal by the end of 2019 will be to have adherence of 60% to the 4 hour recommendation. In order to demonstrate this degree of improvement, I will need 48 subjects in the pre-intervention analysis and 48 subjects in the post-intervention analysis.

Power analysis will be conducted using chi-square modeling for the categorical variable in question. The only two options for each mother will be if she received a breast pump within 4 hours or if she did not. If the data proves to be more complex, then in the future I may consider linear variable and t-tests to evaluate the data.

E. Study Procedures No procedures will be used in the study.

F. Study Drugs No study drugs, approved or experimental, will be used in the study.

G. Medical Device No new medical devices will be used in the study. The study examines the delivery of electronic breast pumps which are already in use within the hospital.

H. Study Questionnaire No questionnaires will be used in the study.

I. **Recruitment of Subjects** This will be a retrospective and prospective chart review. We will apply for a waiver of consent.

J. **Confidentiality** Data will be de-identified and each subject will be assigned a unique study ID. All data will be encrypted on an encrypted, password protected computer.

K. Potential Conflict of Interest None of the investigators have conflicts of interest to report.

L. Location of Study The study will primarily take place on 5 Central and 6 Central of Morgan Stanley Children's Hospital. As the project continues, it may be necessary to implement intervention on 10 Tower, Labor and Delivery floor.

M. Potential Risks To the extent that the study will involve risk, it would be loss of confidentiality by chart review. However, this risk is minimized to the extent possible by de-identifying data and storing data secure, password protected area.

N. Potential Benefits If the interventions prove successful, then children will wind up with earlier, more robust access to maternal breast milk. Additionally, for the parents of the child in the NICU, being able to pump and focus on their ability to contribute to the care of their child may be psychologically protective.

O. Alternative Therapies No alternative or experimental therapies will be employed in the study.

P. Compensation to Subjects No compensation will be provided to subjects.

Q. Costs to Subjects There will be no cost to study subjects.

R. **Minors as Research Subjects** When data is collected from the charts of infants, there will be numerous safeguards upon the data, as described above. No changes will be made to the plan of care of the infants as a result of this study.

S. **Radiation or Radioactive Subjects** Study subjects will encounter no radiation or radioactive substances.

References:

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