The Impact of Increased Parent Presence in the NICU on Parent & Infant Outcomes

#2014-15866

Most recent IRB Review: 1/31/23

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I. Background/Justification:

"Family-centered care (FCC) is an approach to medical care rooted in the belief that optimal health outcomes are achieved when patients' family members play an active role in providing emotional, social, and developmental support" (Gooding et al., 2011, p. 20). FCC is becoming the standard of care for Neonatal Intensive-Care Units (NICUs) and is the standard of care at Ann & Robert H. Lurie Children's Hospital of Chicago. However, programs of FCC differ between hospitals and NICUs. Typical aspects of FCC address, to varying degrees, parent-education, parent/family presence, parent participation in care and decision-making, bereavement, and transition-to-home support. Many benefits of FCC are reported in the literature. These include decreased length of stay (Ortenstrand et al., 2010) as well as improvements in attachment (Affonso, Wahlberg, & Persson, 1989; Feldman, Eidelman, & Sirote, 2002) infant health outcomes such as weight gain (O'Brien, et al., 2013), parent mental health outcomes (Melnyk, Feinstein & Alpert-Gillis, 2006; Shaw et al., 2013) and parent and staff satisfaction (Cooper et al, 2007). Despite documented benefits of FCC, gaps remain in the integration of FCC at the bedside, family participation in FCC programs is inconsistent, and more evidence supporting specific FCC programs is needed (Cooper et al., 2007; Gooding et al., 2011).

Several aspects of FCC are typically addressed by NICUs. Formal and informal training in supporting families is aimed at improving NICU staff communication and collaboration skills. Having an additional staff position designated for family support, for example a March of Dimes Family Support Specialist, is reported to be effective in increasing family supports (Cooper et al., 2007). Support groups and parent-to-parent support groups can be a valuable source of information and support for NICU parents, but care must be taken to assure volunteers and group facilitators are trained and supported. Online and technology-based supports may also serve as a valuable source of 24/7 information and support for NICU families. However, parents need guidance to select sites that provide information that is accurate and current. NICU family education programs including those that support the family's transition-to-home may include bedside and group education sessions as well as written, audiovisual and internet-based parent resources. Education programs and resources are reported to decrease stress and increase confidence in NICU families (Cooper, 2007). Efforts to support family collaboration and shared decision-making such as including families in medical rounds are one of the cornerstones of FCC. FCC programs aimed at increasing parent presence allow parents to build confidence by offering families increased opportunities to participate in their infants' care as well as increased opportunities to access to family education and supports programs in place.

Many benefits of FCC programming have been reported. Several programs including Creating Opportunities for Parent Empowerment ([COPE], Melnyk et al., 2006; Melnyk & Feinsteing, 2009) and the Newborn Individualized Developmental Care and Assessment Program ([NIDCAP], Als et al., 1994; McNulty et al., 2009) report outcomes that include a significantly reduced length of stay. Programs that support practices such as kangaroo care (KC) positively impact bonding and attachment (Affonso et al., 1993; Feldman et al., 2002), and positive infant outcomes including better weight gain, less apnea (difficulty breathing), and better sleep are reported in studies of FCC interventions including KC (Ludington-Hoe et al.,

2004, 2006; Conde-Agudelo, Diaz-Rossello & Belizan, 2003). Several FCC initiatives support improved parent mental health outcomes. Mothers participating in the COPE program reported less stress (Melnyk et al., 2006). Outcomes of professional and peer support programs include less stress, less anxiety, less depression and more confidence (Cooper et al., 2007; Shaw, et al., 2013; Preyde & Ardal, 2003). Parent and staff satisfaction are also improved by FCC initiatives (O'Brien et al., 2013; Cooper et al., 2007).

Despite the benefits of FCC, gaps remain in the integration of FCC at the bedside and significant progress is needed (Gooding et al., 2011). Even specific interventions with clear benefits such as KC have not been fully adopted. In a March of Dimes study of family-centered care initiatives, only 8% of neonatal nurses indicated that their units regularly practiced KC (Cooper et al., 2007). Parent presence in the NICU is variable and impacted by family demographics, culture and social policies. As a result family participation in FCC programs is inconsistent and families do not fully access opportunities to interact with their infant or the parent education and supports available to them. Reynolds et al. (2013) reported infants in one tertiary-level NICU were visited by parents fewer than 5 days per week at baseline and over the hospitalization visiting decreased. More visiting and holding was associated with improved early neurodevelopmental outcomes. Several recent studies have reported positive parent and infant outcomes following implementation of specific FCC programs requiring increased parent presence and participation in care. These positive outcomes include increased weight gain, earlier discharge, increased breastfeeding rates at discharge, decreased parent stress, and increased maternal confidence (O'Brien et al., 2013; Ortenstrand et al., 2010). These programs were implemented outside of the United States (US) and required parent presence in the NICU 8 to 24 hours/day. It is not known whether a program requiring fewer hours/day of parent presence will be a better fit with current US family demographics and social policies; and if they would demonstrate similar benefits.

II. IND / IDE #: N/A

III. Hypotheses / Specific Aims:

The purpose of this pilot study is to compare NICU parent and infant outcomes pre and post a planned unit-wide intervention aimed at increasing parent presence in the NICU at Lurie Children's. The unit-wide family-centered care intervention (FCC intervention) will consist of communicating an expectation that NICU parents be present at minimum 4 hours/day versus the current practice of telling families to "come as much as they can" that has resulted in inconsistent parent presence and participation. This intervention has been approved by the NICU leadership team and is in line with our corporate goal of improving parent engagement.

Specific Research Questions

What is the impact of implementing specific expectations for parent presence in the NICU on:

1) Parent visiting rates, holding frequencies, kangaroo care, and breastfeeding?
2) Maternal and paternal stress?
3) Infant outcomes including weight gain, length of stay, feeding status at discharge, and stress?
4) The NICU's overall parent visiting rates, kangaroo care rates, breastfeeding rates, nosocomial infection rates, Intravenous therapy (IV) infiltrates, medication errors rates and incident (SERS) report rates?

5) NICU staff perceptions of family participation and preparation for discharge?

IV. Characteristics of Participants

Up to 90 NICU infants and one or both of their parents will be enrolled in this pilot study. 45 NICU infants and their parents in the pre-FCC intervention phase and 45 NICU infants and their parents in the post-FCC intervention phase. At least one parent (mother or father) of the infant being admitted into the NICU is required for participation in the study; at most both parents can participate. As the Lurie Children's NICU admits infants of all gestational ages and FCC is recommended in the literature for all NICU families, subject enrollment will be split so that 50% of the infant/family subjects in both the pre- and post-FCC intervention phases of the study will consist of preterm infants ≥28 weeks gestation and <36weeks gestation and 50% will be term infants > 37 weeks gestation. Infants admitted to the NICU within the first 2 weeks of life will be considered for enrollment in the study. As the study aims to study infant and parent outcomes through discharge, infants hospitalized in the NICU beyond 3 months of chronological age or who expire or are transferred to another nursing unit or facility prior to discharge from the NICU will also be excluded from the study. Infants admitted to the NICU from home will also be excluded from the study.

We currently have 10 patients/families enrolled in the study. The NICU currently admits 600+ infants per year. The previous enrollment criteria requiring that infants be admitted within 7 days of NICU admission and excluding infants transferred from another NICU after one week of life limited our ability to enroll a greater number of infants. We are confident the number or NICU admissions and our revised enrollment criteria will allow us to meet our increased sample size of 90.

Although we have increased our overall sample size, we will continue to exclude non-English speaking families from the study due to the low numbers of these families in the NICU. Since last January only 20-25 NICU families have been Spanish speaking, and while we occasionally admit non-English speaking families with other primary languages such as Arabic, their numbers are even smaller. In addition, a percentage of the non-English speaking NICU families are admitted from home and would be excluded from the study. Therefore, the representation of non-English speaking families in our potential subject pool is very small and non-English speaking families will continue to be excluded.

V. Summary of Procedures

Up to 90 NICU infants and one or both of their parents will be enrolled in this study at Lurie Children's. Admission logs for the NICU will be reviewed daily to screen eligible subjects. The screening may be done by the Principal Investigator (PI) or a member of the study team. Parents of prospective subjects will be approached as soon as possible after admission. Following informed consent, collection of study data will begin as outlined below. Infants' and their parents will remain in the study as long as the infant remains in the NICU.

A team of NICU staff nurses has been recruited to serve on the study team; they have completed the human subjects' education requirement and they will be trained by the PI to consent families and collect data.

Pre-FCC Intervention Phase

A convenience sample of 45 NICU infants meeting subject criteria and admitted during a three-month period prior to the implementation of the planned unit-wide FCC intervention with one or both of their parents will be recruited to participate in the pre-FCC intervention phase of the study. Data collection for the pre-FCC intervention will include Infant research measures, Parent research measures, NICU unit-wide research measures, and a NICU staff survey. These are described in detail below.

Infant research measures

For purposes of the study, infants' stress will be measured using Salivary Cortisol levels which will be obtained using an oral swab by a member of the NICU nursing staff. Although salivary cortisol levels are not routinely measured in infants in Lurie Children's NICU, swabbing an infant's mouth presents minimal risk to study infants. Salivary cortisol is a simple and effective biomarker of stress and

has been used to measure reactivity to and recovery from a stressor in infants. In this study, trends in infant group salivary cortisol data from different time points during a NICU stay will be compared pre- and post- a FCC intervention aimed at increasing parent presence in the NICU. Infant salivary cortisol levels are subject to a high degree of variability and may be impacted by oral intake, diurnal rhythms, stressful procedures such as heelsticks, and developmental changes. When evaluating a group of infants' responses to stressful events, improved accuracy may be achieved by using a consistent collection technique that includes screening for oral intake or stressful procedures, consistent timing for collection to address diurnal rhythms, and consistent age at collection to address developmental changes (Tryphonopoulos, et al., 2014). In this study salivary cortisol levels will be collected during different time periods: on admission to the study, every 4 weeks while in the NICU , and on during the week prior to discharge. To avoid potential influences on cortisol levels, infant salivary cortisol levels will be collected between the hours of 4 and 11 am, prior to any anticipated standard of care procedures that might initiate a physiologic stress response in the infant. To avoid components that can disturb salivary cortisol analysis, nursing staff will review the infant's chart to assess whether the infant has taken anything by mouth and will wait one hour before collecting salivary cortisol following oral intake. Nursing staff will also check the mouths of infants receiving tube feedings for formula and will wait one hour before collecting salivary cortisol if formula is found (Mitchell, Chang, Yates &, Hall, 2012). Prior to the study, the written procedure for collecting infant salivary cortisol levels, developed by the PI in conjunction with Lurie Children's Laboratory Services, will be reviewed by the NICU nursing staff (see Infant Salivary Cortisol Instruction Sheet in Appendices). There are no reference levels for Infant Salivary Cortisol levels; therefore, no reporting of abnormal levels will be necessary.

Other infant research measures pre-FCC intervention will include demographic and treatment data, visiting rates, holding frequencies, rates of kangaroo care, breastfeeding rates, infant weight gain, length of stay, and feeding status at discharge. Demographic and treatment data to be collected will include data needed to assign a score for severity of illness and complications using the Neonatal Medical Index ([NMI], Korner et al., 1993) which will be used to determine comparability of the pre-post subject group from the heterogeneous NICU population (see NMI and Infant Data Sheet in Appendices). This infant data is present in the child's medical record as part of standard care and will be collected via chart review by members of the study team as de-identified data using a subject number assigned to the infant. For purposes of the study the following operational definitions will be used and data will be documented accordingly.

a. *Visiting rates* will include family visiting rates in hours per week.
b. *Holding frequencies* will include the number of days per week that an infant is held in a traditional manner by the family, not skin-to-skin, one or more times per day.
c. *Kangaroo care rates* will include the number of days per weeks that an infant is held skin to skin one or more times per day.
d. *Breastfeeding rates* will include the both number of weeks that a mother provides pumped breast milk for her infant in the NICU, and whether the infant is breastfeeding or receiving breast milk feedings at discharge.
e. *Infant weight gain* will be calculated in grams/day of weight gain during the infant's NICU stay as follows. Data on infant weights which are done as part of standard NICU care will be obtained from chart review. Infant weight difference between birth and at discharge will be divided by the number of days from birth to NICU discharge.
f. *Length of stay* will be recorded as number of days from birth to NICU discharge.
g. *Feeding status at discharge* will be recorded as feeding route at discharge and percentage of feedings being taken orally.

<u>Parent research measures</u>

For purposes of the study, demographic data will be collected from the infants' parents' pre- FCC intervention including their age, relationship status, number of other children, education level, employment status, and distance traveled to the NICU. Also for purposes of the study, parent stress will be measured using Salivary Cortisol levels and the Parent Stress Scale: Neonatal Intensive Care Unit

([PSS: NICU], Miles, 2002). Salivary cortisol levels are not routinely done on NICU parents at Lurie Children's; however, the collection of a small sample of saliva represents minimal risk to an adult and takes only 5-6 minutes to collect. Salivary Cortisol levels will be obtained from study parents once on admission to the study, every 4 weeks while their infant is in the NICU, and once the week of their infant's NICU discharge while the parent is visiting the NICU. To avoid components that can disturb salivary cortisol, nursing staff will ask parents when their last oral intake occurred. If the parent report eating or drinking in the previous hour, collection by the NICU nurse of the salivary cortisol will be delayed until a one hour interval from the last oral intake has occurred. Prior to the study, the written procedure for collecting adult salivary cortisol levels, developed by the PI in conjunction with Lurie Children's Laboratory Services, will be reviewed by the NICU nursing staff (see Adult Salivary Cortisol Instruction Sheet in Appendices).

We have discharged home 7 of 10 families enrolled under the original research plan. Of the remaining 3 families, one set of parents has already missed the window for additional salivary cortisol sampling scheduled every 4 weeks while the infant is in the NICU under the revised research plan. Therefore, we will not re-consent in order to collect additional salivary cortisol samples for any family enrolled under the original research plan.

The PSS: NICU is a well-established self-report tool for NICU parents. Using a Likert scale parents respond to sources of stress in 3 domains, Infant Behavior and Appearance, Sights and Sounds, and Parental Role Alterations. Construct validity ($r=0.46$-0.61, $p<.001$) (Franck, Cox, Allen & Winters, 2005) and internal consistency ($\alpha>0.70$) (Miles, Funk & Carlson, 1993) have been established for the PSS: NICU. Where both parents are enrolled in the study with an infant, PSS responses and salivary cortisol levels will be collected for each parent independently. The PSS will be administered within one week of admission to the study and again the week of discharge. It will take parents 20-30 minutes to complete the PSS: NICU.

Unit research measures

For research purposes, unit-wide data will be also be collected pre-FCC intervention. This data will be received as aggregate data without patient identifiers and will consist of unit-wide visitation rates, rates that NICU infants are held by a family member, kangaroo care rates, breastfeeding rates, nosocomial infection rates, and numbers of IV infiltrates medication errors and overall incident (SERS) reports. Rates of nosocomial infection rates, IV infiltrates, breastfeeding rates, medication errors and overall incident (SERS) reports are currently available and reported to NICU leadership as aggregate data; these measures will be reported to the study team by the NICU leadership team. The average daily census, visitation rates, rates families held NICU infants, and kangaroo care rates as defined by the study's operational definitions above will be reported to the PI as aggregate unit-wide data without patient identifiers by a member of the Research Informatics staff of the Stanley Manne Children's Research Institute.

NICU Nursing staff survey

NICU staff perceptions of parent presence in the NICU and preparation for discharge pre- the FCC intervention will be measured using a staff survey designed for the study (see appendices). Participation in the staff survey is voluntary and staff responses will be free from identifiers so that they will be anonymous. A link to the staff survey will be sent to staff during the three-month period prior to the implementation of the planned unit-wide FCC intervention and will take them 15-20 minutes to complete. A request for a waiver of consent and waiver of documentation of consent has been completed for the NCIU staff survey (see appendices).

FCC Intervention

The FCC intervention consists of a planned NICU-wide change aimed at improving family presence and participation in the NICU. It will occur following the three-month pre-FCC phase of the study (see Section X. Timetable). This planned NICU-wide change will consist of communicating to all NICU families that the NICU's expectation is that at least one parent will be present 4 hours per day in the NICU. This FCC intervention will be communicated during the admission of their infant via a parent letter (see appendices) included in the admission packet that will be given to all NICU families. NICU family supports already in place will be available to all NICU families during all phases of the study.

These family supports include parent sleep rooms, the Ronald McDonald house, parking support, breastfeeding support, weekly parent education and scrapbooking groups, educational materials, parent to parent programs, and family support staff. NICU staff input was obtained at several NICU staff committee meetings prior to proposal development. The FCC intervention of communicating an expectation of family presence in the NICU 4 hours/day was selected as it was felt by the NICU staff it could be a feasible timeframe for families managing siblings or employment while their infant is in the NICU. There will not be any negative consequences for families who do not comply with this expectation.

Supports for the NICU nursing staff providing FCC at the bedside will include reviewing the parent letter explaining the FCC intervention. Additionally, NICU staff will be supported in meeting the FCC needs of families via monthly staff meeting discussions and currently available clinical resources including the NICU family support services team including social work, child life and the Parent-wise program.

Post-FCC Intervention

A convenience sample of 45 NICU infants meeting subject criteria and admitted during a three-month period following the initial implementation of the planned unit-wide FCC intervention with one or both of their parents will be recruited to participate in the post-FCC intervention phase of the study. Data collection for the post-FCC intervention will include the same infant research measures, Parent research measures, and NICU unit-wide research measures collected in the pre-FCC phase of the study. NICU staff will be asked to complete the same survey completed in the pre-phase of the study.

VI. Risks and/or Ethical Issues

There are no physical risks to parents or infant subjects. Saliva for salivary cortisol levels will be collected by placing an oral swab in the parents' and infants' mouths. This should not be uncomfortable.

The study intervention is a planned NICU-wide change that consists of communicating specific expectations for parent presence in the NICU (FCC intervention). There will not be any negative consequences for parents that are not able to or choose to meet these expectations.

The risk of breach of privacy and confidentiality exists. Given the private room lay-out of the NICU, privacy and confidentiality will be maintained as discussions regarding participation in this research will occur in the privacy of the patient's own room.

VII. Benefits

There are no direct benefits for participation in the study. The study hopes to learn how parents' presence in the NICU impacts parent and infant stress and impacts infant outcomes. This information may be helpful to NICU staff and families in the future.

VIII. Informed Consent Process:

Admission logs for the NICU will be reviewed daily to screen eligible subjects. The screening may be done by the PI and/or a member of the study team. Parents of prospective subjects will be approached as soon as possible after admission to the NICU. The study will be explained by the PI or a member of the study team and a copy of the consent form will be left with the parent(s) for review. It will be explained that enrollment must occur within the first week of admission into the NICU, and that the time from the first explanation of the study until a week following admission will be allowed for continued review of the consent form and to ask questions of research and clinical staff. To avoid coercion, it will be explicitly explained that there is no obligation to participate in the study and that the medical care the infant has received in the NICU will not be affected should parents choose not to sign the consent form. Parents will also be advised that, should they sign the consent form, they will have the right to remove their child from participation in the study at any time.

A request for a waiver of consent and waiver of documentation of consent is being requested for the NICU Nursing Staff for their participation in the survey. I believe the NICU staff survey meets the requirements necessary to be considered for Waiver of Informed Consent because 1) the survey presents no more than minimal risks to human subjects, 2) survey responses will not include identifiers, therefore the waiver will not adversely affect the rights or welfare of the NICU staff completing it, 3) the research questions related to NICU staff perceptions of family participation and preparation for discharge could not be practically carried out without the survey, and 4) upon completion of the study the NICU staff will be provided with a summary of the survey results. I believe the NICU staff survey also meets the requirements necessary to be considered for Waiver of the Requirement for Documented Informed Consent, because 1) the only record linking the NICU staff members completing the survey to the study would be the consent document, and 2) the survey presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Finally, basic information about the study including the basic elements of informed consent will be provided to NICU staff in the Introduction to the Survey (see NICU staff survey for details).

IX. Measures to Protect Privacy and Confidentiality of Participants

For purposes of the study infants and their parent(s) will be identified by a study number and personal identifiers will not be recorded. All study data will be maintained in a locked file in the office of the PI. Computerized data will be maintained in password protected computer files maintained by the PI. Unit data will be reported and recorded as aggregate unit-wide data only with no patient identifiers. Participation in the Nursing staff surveys will be voluntary and responses will be free of identifiers.

X. Data Management and Statistical Analysis:

Data will be recorded on a computerized spreadsheet maintained by the study team and saved in a password protected file on the L drive within Lurie Children's computer system; only members of the study team will have access to the study files. The study team will monitor the data for accuracy.

Prior to data analysis the infants will be assigned a score using the Neonatal Medical Index (NMI) developed by Korner (1993). The NMI identifies the presence of and degree of illness and complications that may influence infant outcomes and will assist in determining comparability of the pre-post intervention groups from the point of view of illness severity; and the NMI has been similarly used in a previous study by the author (Horner, et al., 2014).

Descriptive statistics will be calculated for all measures. Mixed repeated measures ANOVA and/or ANCOVA will be employed. Data will be analyzed using SPSS 28.0. Level of significance will be $\alpha=0.05$.

XI. Costs, Compensation, and Participant Reimbursement:

There will be no costs to participants. There is no compensation, reimbursement or incentives for participation in this study.

XII. Provisions for Research Related Injury

Risks to infants and their parents' are minimal and injuries are not anticipated. Should an injury occur, medical care will be provided to the infants by the NICU staff at Lurie Children's. Parents of the infants' will be responsible for the cost of their medical services. Although the risks are minimal, if a parent is injured, medical facilities and treatment are available, however, parents will be required to pay a reasonable fee for such care.

XIII. References:

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