

GPS (Giving Parents Support): Parent Navigation After NICU Discharge

NCT02743472

Study Protocol

Updated/approved by Children's National IRB: 2/15/17

PI: Karen Fratantoni, MD, MPH

GPS (Giving Parents Support): Parent Navigation After NICU Discharge

Background:

NICU parents experience high levels of stress, anxiety, and depression, and low levels of self-efficacy. Neonates comprise one of the largest groups of medically complex infants in the United States. Of the 4 million live births in 2012, 11.5% (~460,000) were born preterm at < 37 weeks gestation¹. The District of Columbia alone has a higher rate (12.8%) of preterm infants, which is 11% higher than the national average. The vast majority of infants born preterm and ~1% of full-term infants with significant illnesses at birth (e.g., congenital anomalies) will require care in a neonatal intensive care unit (NICU), and ~30% of infants being discharged from the NICU (“NICU graduates”) annually (110,000 babies) require supplementary short-term or on-going specialty care² and have increased risk of long-term disability, including cerebral palsy, deafness, blindness, and neurodevelopmental impairment³⁻⁶. At discharge, this large cohort of neonates and their families face tremendous challenges as they transition from a highly structured medical environment to a less structured home environment^{7,8}. Some challenges identified include feeling unprepared to care for their infant at home despite extensive teaching in the NICU setting, feeling socially isolated as the typical celebratory process of giving birth and going home with baby has been disrupted by a serious medical condition and prolonged hospital stay. Additionally, depression and anxiety among mothers of infants have been shown to be associated with infant feeding difficulties, suboptimal parenting practices, and altered health care utilization.

NICU graduates can be classified as children with special health care needs (CSHCN), a group comprising 15% of US children,⁹ who “have or are at increased risk for a chronic physical, developmental, behavioral, or emotional condition and who also require health and related services of a type or amount beyond that required by children generally.”¹⁰ CSHCN consume a majority of pediatric health care expenditures. The American Academy of Pediatrics posits that all children, including CSHCN, should receive accessible, continuous, comprehensive, family centered, coordinated, compassionate, and culturally effective care within a medical home.¹¹ The inclusion of CSHCN in a medical home improves health related outcomes,¹² but poses challenges on a practice level, as these patients need more sustained and intense interactions.

Parent navigation is a unique patient-centered intervention in which parents with experience caring for their own CSHCN offer peer to peer support and mentoring to another parent of a child with a special health care need. In 2008, Children’s National instituted a Parent Navigation program, in which Parent Navigators (PNs), who are parents of children with special health care needs (CSHCN) are employed by CN to provide peer-peer support to other parents of CSCHN. They provide their own personal experience and expertise in navigating the often confusing and frustrating health care systems. Specifically, although the PN model is based on self-efficacy and social support models, there are no published studies on the impact of PN on parental self-efficacy, depression, stress, and infant health outcomes. We believe NICU graduates and their caregivers would benefit from peer-peer support provided by PNs after discharge. Currently, there are no data regarding the impact of PNs on patient and family outcomes of the NICU graduate.

Preliminary Studies:

As a first phase of this study, we conducted focus groups with parents of recently discharged NICU infants (4 focus groups, n=18 participants), parent navigators (1 focus group n=3), interviews with parents (n=2), NICU social workers, case managers, and nurses (1 focus group, n=23); NICU providers (1 focus group, n=5) and community providers (n=2). (See Pro00004397 for details). Our intervention is informed by this data.

Additionally, Dr. Tuchman (Co-PI) has recently completed a similar randomized controlled care coordination intervention focused on a population of youth with special health care needs transitioning their pediatric-focused care from Children's to community adult practices using similar methodology and outcomes measurement strategies.

Specific Aims:

Infants who are discharged from the NICU almost invariably have high levels of health care needs in the first year after discharge, requiring multiple sub specialist visits, medications, and/or medical technology needs. Parents of NICU infants are often overwhelmed by the needs of their infants after they are discharged home and frequently have few supports to help them cope. This study will investigate the impact of peer to peer support through a Parent Navigation program for NICU graduates and their parents. The study aims will be achieved through a randomized controlled trial of Parent Navigation using a care resource notebook as the control intervention.

Our specific aims are to:

1) Determine if Parent Navigation increases overall parental self-efficacy and decreases stress among parents caring for a child with a special health care need during the 12 months after NICU discharge.

Hypothesis 1a: Parent Navigation will increase parental self-efficacy, when compared with the control group.

Hypothesis 1b: Parent Navigation will decrease parenting stress, when compared with the control group.

2) Determine if Parent Navigation improves overall levels of anxiety and depression in parents of children with special health care needs during the 12 months after NICU discharge.

Hypothesis 2a: Parent Navigation will improve parent anxiety, compared with control group.

Hypothesis 2b: Parent Navigation will lessen parent depression, compared with control group.

3) Determine if Parent Navigation positively impacts on infant health outcomes during the 12 months after NICU discharge.

Hypothesis 3a: Parent Navigation/Intervention group will have significantly fewer hospitalizations when compared with control group.

Hypothesis 3b: Parent Navigation group will have significantly fewer emergency department (ED) visits, when compared with control group.

Hypothesis 3c: Parent Navigation group will result in improved immunization status, when compared with control group.

Hypothesis 3d: By supporting parents' emotional function, infant developmental progress will be enhanced.

Research Design and Methods

The evaluation of the Parent Navigation NICU to home program will use a randomized trial design. We will do so by recruiting a population of parents who have an infant in the Children's National NICU, half of whom will receive enhanced usual care by provision of a NICU care notebook and half of whom will receive the same enhanced care- including care notebook- plus Parent Navigation (intervention). All will be patients in the NICU who are discharged from the CNMC NICU. Group assignment will be by randomization, stratified by birth weight (≤ 1500 grams or >1500 grams). The design incorporates extensive measurement of baseline attributes to assess the comparability of intervention and enhanced control groups at inception.

We aim to enroll $n=300$ parents of infants receiving care in the Children's National NICU who are discharged from the CNMC NICU. CNMC has a Level IV NICU which receives a large number of complex cases. To allow for generalization of study findings to other NICUs and other centers, we will enroll all patients discharged from the CNMC NICU.

Study personnel will identify eligible NICU patients by reviewing NICU census data or through the use of the PowerTrials Prescreening function. PowerTrials is a HIPAA-compliant application that is integrated into the Children's National Cerner electronic medical records system (PowerChart). Study inclusion and exclusion criteria will be used to create a Prescreening Rule. A screening engine in PowerChart will compare the criteria to patient data within the medical records system, and a list of potential study subjects will be generated.

Research study staff will approach parents anticipating discharge within 1-2 weeks to invite their participation and, as appropriate, obtain informed consent. If parents of eligible patients are not available, we may contact a parent by phone to set up a time to discuss the study in person. We will obtain in person signatures of consent as appropriate before enrolling potential participants in the study. Recruitment will continue in this fashion until the required sample is enrolled.

Inclusion criteria include:

NICU patients discharged from the CNMC NICU. One parent participant per NICU patient will be identified and enrolled as the participant.

Exclusion criteria include:

Exclusion criteria include if the infant is not being discharged with a custodial parent (e.g., in custody of Child Protection Services), neither parent can complete an interview in English, the parent who will be providing most of the care is younger than 18 years of age, or the parent/caregiver has plans to leave the DC metropolitan area permanently within the following year.

We are limiting the sample to parents of NICU patients that are >18 years of age, because we are interested in adult behavior and concerns. There are no exclusions based on ethnicity or gender; however, all participants will need to be able to complete the interviews in English. We will selectively enroll the one parent/guardian of infants with the most proficient grasp of English. We do not anticipate that this will limit our inclusion of Hispanic families. Upon review of the past 6 months of NICU discharges, 11% report Hispanic ethnicity. Among those- 92% speak English and only 8% speak Spanish and no English.

Study Design and Data Collection:

Following consent and enrollment, the baseline interview will be conducted in person while the infant is still in the NICU. To assure a consistent methodology for collecting subsequent data, all subsequent interviews will be conducted by telephone after NICU discharge. Participants will complete a short semi-structured interview and a questionnaire of measures detailed below at each time point (see data collection sheets and phone script in documents section). Items and instruments were carefully selected to minimize participant burden. All participants will be interviewed and complete instruments at enrollment and 1 week; 1 month; 3 months; 6 months; and 12 months post NICU discharge.

The CESD is a measure to identify depression and is administered at baseline, 1 month, 3 months, 6 months and 12 months. The score is tabulated in redcap, and a report identifies scores of 10 or greater. If a participant has a score of 10 or greater on the CESD, the research team leadership (one of the PIs or co-investigators) will contact the participant by phone within 1 week to discuss the elevated score. Please see telephone script for elevated CESD. The team member will then send a letter and resources to the family. Please see attached letters and information sheet detailing perinatal mental health resources. If a participant cannot be reached by phone, a letter with resources will be sent. If a participant has a subsequent score of 10 or greater on the CESD, a follow up letter and resources will be mailed within one week of the elevated score.

Procedures for data collection will be the same for intervention and control group participants. We will have text telephone technology (TTY) available for phone interviews for participants with hearing impairment. RAs will be fully trained on interview procedures and will be supervised by Drs. Fratantoni and Tuchman.

Assessment tools include (all are uploaded in Documents section):

1) Perceived Maternal Parenting Self-Efficacy (PMP S-E) tool: 20 items. Mothers' perceptions of their ability to parent (maternal parenting self-efficacy) are a critical mechanism guiding their interactions

with their preterm newborns. A robust measure is needed which can measure mothers' perceptions of their ability to understand and care for their hospitalized preterm neonates as well as being sensitive to the various levels and tasks in parenting. This will be administered at baseline, 1 week, 1 month, 3 months, 6 months and 12 months post NICU discharge.

2) State-Trait Anxiety Inventory (STAI). This consists of 20-items total, and respondents indicate transitory anxiety on a 4-point Likert scale. The STAI has been used extensively in both medical and non-medical populations, with excellent psychometric properties. The inventory contains the State Inventory (10 items, scale Y1), which will be administered at baseline and 1 week, 1 month, 3 months, 6 months and 12 months post NICU discharge. The trait inventory (10 questions, Y2) will be administered only at baseline.

3) Depression/Anxiety Measure: Parent depressive symptoms will be assessed using the Center for Epidemiological Studies- Depression Scale (CES-D) short form. This 10-item self-report measures depressive affect, somatic symptoms, positive affect, and interpersonal relations. Items are rated on a 4-point Likert scale. CES-D has adequate test-retest reliability and correlates well with clinical ratings of depression severity. This will be administered at baseline, 1 month, 3 months, 6 months, and 12 months.

4) Social Support: Parental perceptions of social support will be measured with the Multidimensional Scale of Perceived Social Support (MSPSS). This 12-item self-report scale includes respondents' support from family, friends, and significant other. The MSPSS has good internal and test-retest reliability and adequate construct validity. This will be assessed at baseline and 1 week, 3 months, 6 months, and 12 months post NICU discharge.

5) PSS: Parental Stressor Scale: The Parental Stress Scale is a self-report scale that contains 18 items representing pleasure or positive themes of parenthood (emotional benefits, self-enrichment, personal development) and negative components (demands on resources, opportunity costs and restrictions). This will be assessed at baseline and 1 week, 1 month, 3 months, 6 months, and 12 months post NICU discharge.

6) Parental NICU stress scale. PSS:NICU, a PROMIS measure. Will be administered at baseline only- 46 items.

7) Functional Status Scale is a measure of function in 6 areas: mental status, sensory, communication, motor function, feeding, and respiratory. The FSS will be performed at baseline and at 12 months, along with the developmental evaluation.

8) Perceived Stress Scale (Sheldon Cohen, 10 items) is a measure of the perception of stress. It will be performed at baseline and at 1 week, 1 month, 3 months, 6 months and 12 months after discharge.

Complete contact information will be collected at baseline and updated at each time point, including mobile numbers and contact information for someone who will know the whereabouts of the participant and be able to assist in locating them as needed.

Participants will be reimbursed for their participation in data collection. Compensation will be \$20 per each data collection time point and \$50 for in person developmental assessment by Dr. Penny Glass (Co-I) in Developmental Clinic at age 12-15 months. Our previous experience with longitudinal research in this population suggests that this amount provides adequate incentive without being coercive.

Infant health outcomes:

Infant health outcomes will include health care utilization (ED visits, hospitalizations, specialty visits, primary care visits) and immunization status.

- Health care utilization:

At each interview, parents will provide information about ED visits, hospitalizations, specialty visits, and primary care visits during the period since the prior interview. All parents/participants will be provided with a calendar to keep track of these encounters for easy recall. We will measure the total number of ED visits, hospitalizations, specialty visits, and primary care visits during the 12 month follow-up period post NICU discharge.

- Immunization status is a frequent measure for use of preventive medical care services and is easily verifiable. We will use receipt of vaccines between NICU discharge and 12 months of age as the outcome measure. We will consider receipt of 3 diphtheria-tetanus acellular pertussis (DTaP) vaccines, 3 Hemophilus influenzae b (HIB) vaccines, and 3 pneumococcal conjugate vaccines (PCV-13) as fully immunized. We will ask the primary caregiver to complete a release of medical information (for immunization records only) upon enrollment. We will obtain immunization records by sending the release to the primary care pediatrician or, when applicable, from the DC or Maryland immunization registry, which is available to Children's National health care providers with a password.

- Developmental testing between 12-15 months of age (or around 1 year corrected age if born prematurely). We will share the results with parents and pediatrician upon participant's request. Scores for five developmental domains (cognitive, language, motor, social-emotional and adaptive/behavioral) and the composite score for the Bayley Scales for Infant and Toddler Development TM, Third Edition (Bayley-III)(Pearson Educational) will be compared. Patients will be assessed in Developmental Clinic by Dr. Penny Glass and her team. At the end of the assessment parents will be provided with immediate feedback and suggestions for ways to help the baby at home. A brief letter is sent to the pediatrician with copy to the family (and medical record). The full time for the assessment is about an hour. The parent is present, and the baby sits on parent's lap. Dr. Glass' staff will set up the appointment when they are enrolled in the study and then have the study coordinator help with reminders. Parents can change the day/time to make it suit their own schedule. If needed, we will provide testing on Saturday to accommodate parents' schedules and to reduce burden.

If a participant has already had the Bayley-III administered at CNMC within the participant's designated study window, the data will be used, and family will qualify for a gift card.

Additionally, infant's medical records will be reviewed at baseline and at 12 months. See Data collection sheet in Documents section.

Description of Intervention:

Care notebook: All participants will be provided with a care notebook designed specifically for this study. It is an enhanced version of the resource notebook developed for use by the current parent navigators at CNMC, and is used to organize the care of medically complex children. The version of the care notebook in this study includes information important for NICU graduates, including available community resources, guidance on advocating for a child with special needs, healthcare providers and educational systems, and has sections where the parent or a healthcare provider can include information important for the child's care (e.g., medications, appointment calendar, care plans, seizure logs, therapy goals, dietary schedules).

Parent Navigation: Once parents/patients are enrolled, all participants will receive a NICU care notebook as described above. Within 24 hours, using a REDCap-based randomization schema built by Dr Carty (Co-I) and blinded to the rest of the study team, participants will be randomized to either the control or intervention group. Those randomized to the control group will not receive any Parent Navigation care but will receive the usual care offered in the NICU. Study personnel will notify control participants of their assignment to the control group. We do not want to add any additional stress for these families, and if left wondering and waiting their group assignment, we are concerned we may cause undue stress. Parents in the Intervention group will be introduced to a Parent Navigator while in the NICU, prior to discharge and following informed consent and enrollment. Parents can contact the Parent Navigator at any time after the initial meeting. If the Parent Navigator has not been contacted by the parent following enrollment or after discharge home from the NICU, the Parent Navigator will contact the parent within 2 business days after discharge to assess how the family is coping, answer questions, and provide necessary resources. For those randomized to the intervention group, the study staff will obtain a signed release to send an information sheet to the identified primary care physician to notify the provider that his/her patient has been enrolled in the study and will receive parent navigation services. The letter will clearly state the roles/responsibilities of the parent navigator.

The details of the intervention are as follows:

Navigator training: An established Parent Navigator program has been led by Dr. Michelle Jiggetts (project coordinator), who is responsible for training and supervising Children's National Parent Navigator Program. Parent Navigators will be recruited specifically for serving families of NICU patients and will be the main source of the intervention in this study. Curriculum guide is attached in Documents Section.

Control Group: To assist with the transition to home care, families in the control group will be provided with the same care resource notebook.

End Points:

Our endpoints are:

1) Data collection: to enroll n=300 (n=150 in each group) and collect data for 12 months after NICU discharge.

2) Data Analysis and writing/disseminating (Abstracts, Manuscripts, and other reports): completion of data analysis and papers accepted for publication in peer reviewed journal(s).

Statistical Considerations:

We will conduct intent-to-treat analyses to assess effects of the PN intervention such that randomized families will be analyzed according to their assigned intervention group, regardless of departures from the randomized intervention. While it is possible that families may seek some type of parental support independently of the intervention, these potential effects may be evaluated in sensitivity analyses. Our analysis strategy will first compare baseline characteristics between the PN and control groups to evaluate the balance produced by randomization. It is expected that randomization with stratification on one key confounder of birth weight (≤ 1500 grams or >1500 grams) will result in a balanced distribution of factors between the PN and care resource groups on most, if not all factors. However, even with randomization some imbalance may occur on a few factors and it is important to identify such factors, as these are the ones that need to be controlled during analysis.

Aim 1a. and 1b. The outcome measures involved in this aim (e.g., parenting self-efficacy measured using the PMP S-E and perceived stress scale), are derived from multi-item scales and will be treated as continuous measurements. For each scale, the mean score after baseline will be assessed at each of the visits (1 week, 1 month, 3 months, 6 months and 12 months). The overall mean difference from baseline for each of the scales between the two intervention groups will be used to evaluate Aim 1. We will assess the overall change in scores for the self-efficacy and depression scales, i.e. the population averaged effect of the intervention on changes in self-efficacy and depression, using a generalized estimating equation (GEE) model to account for the correlation between the repeated change measurements among primary care givers. The GEE model is reasonably robust to missing data. We will use an exchangeable correlation structure, but in sensitivity analyses, will also test unstructured correlation and compare parameter estimates. The main independent variable in these analyses is intervention group, however we will also include (if necessary) a cross-product term of group-by-time which will enable us to estimate differences between the intervention groups over time. The group-by-time term will be included only if it is statistically significant. The model will include covariates reflecting the randomization stratification variables, and other covariates only if imbalances are observed in the randomization groups at baseline. In addition, we will use the model to plot the change in parental self-efficacy or parenting stress over time-by-group with 95% CI around each time point estimate. The degree of change at 3-months will allow us to assess the rapidity of any effect of intervention and a descriptive comparison of the differences between the groups at 6- and 12-months will allow us to assess the degree of persistence of any effect. We will consider the difference between groups to be statistically significant when the 95% confidence intervals around the difference do not include 0.

Aim 2a. and 2.b. will compare measures of anxiety using the STAI, and depression using the CES-D in primary caregivers from the intervention and control groups. The independent variable will be the intervention group in both models. If necessary, the models will include covariates known to impact parental depression and anxiety (if different between the groups) and stratification variables. We will estimate and compare the covariate adjusted mean difference in the scores between the intervention groups using GEE models as described above (Aim 1). The difference will be considered to be statistically significant if the 95% CI around the difference fails to include 0.

As in Aim 1, group-by time-interaction models will be used to evaluate differences between the groups over time.

Aim 3. The NICU graduates may experience multiple ED visits or hospitalizations any time after baseline. The number of ED or hospitalization counts will be summed for each of the intervention groups. To assess differences between the intervention groups for each of the outcomes (ED visits or hospitalizations), we will use the Wilcoxon–Mann–Whitney two-sample rank-sum test, which is appropriate for use with nonparametric data, such as the count data from this aim. We will define the outcome, improved immunization status, as receipt of two diphtheria-tetanus-acellular pertussis (DTaP) vaccines, two Hemophilus influenzae b (HIB) vaccines, and two pneumococcal conjugate vaccines (PCV-13) by the end of the observation period (12 months after baseline). This binary outcome will be contrasted using an unpaired t-test with unequal variances to measure the hypothesis that the intervention results in improved immunization status.

Sensitivity Analyses. In sensitivity analyses, we will explore the effect of departures from assumptions made for the main analysis. A key assumption in our analyses is that missing data are missing at random, and groups who are and are not lost to follow-up are similar. We will compare characteristics of families who are, and are not, lost to follow-up. If significant differences between these two ($p < 0.05$) are observed, we can test for intervention effects, but with the assumption that individuals with missing data have worse outcomes. We will then report these ‘worst case’ scenarios and report any changes in the clinical interpretation of the trial.

Sample Size & Power. We calculated power to detect projected differences between the intervention groups for the 3 primary outcomes. All computations are based on a projected sample size of 300 families of NICU infants (i.e. 300 primary care giver evaluations, and 300 NICU infant outcome evaluations) with randomization into 2 equal groups of 150, with data collected over multiple time points during the 12 months of follow-up post discharge. In Aims 1 and 2, we will have up to 5 repeated measures after baseline (1-week, 1-month, 3-months, 6-months, and 12-months), which increases our statistical power for those aims. We assumed a modest within-subject correlation of 0.50 between these repeated measures. Using Bonferroni correction, we adjusted alpha (0.05) for the number of primary outcomes, $n=3$. For Aim 1, we estimate that we will have excellent power (93%) to detect differences in parental self-efficacy scores as small as 0.33SD. This estimate is based on PMSPE score distributions as reported in the literature. For the main infant outcome of number of hospitalizations during the 12-month follow-up post discharge period, we estimate that we have excellent power (99%) to detect a difference of 1 in the median number of hospitalizations between the groups. Given our conservative

assumptions, including modest correlation ($r=0.5$) between repeated measures and Bonferroni correction for the number of primary outcomes, we believe that our sample size ensures sufficient power to measure clinically relevant differences between the intervention groups.

Consent and Recruitment:

Recruitment will occur in the NICU. Research staff will use an information sheet to introduce the study to parents, approach parents in person (in the NICU, or contact them by phone to introduce the study and obtain contact information from those who are interested. Interested parents will be contacted by research staff, study details will be described, and parents who qualify and agree to participate will sign written informed consent. Parents wishing to discuss the study will also be given an option of discussion over the phone and then the option of: 1) sign, scan, and email the consent back, or 2) sign and fax the consent back, 3) mail the consent back in the self-addressed envelope provided or 4) sign and bring it with them the next time they are at the hospital. The parent will then complete baseline surveys (see Procedures) and given a care notebook. The participant will be randomized to the control or intervention group. For those randomized to the intervention group, a Parent Navigator will introduce themselves prior to discharge. Participants who are in the control group will be notified that they were randomized to the control group as to not create any additional sources of stress or uncertainty.

Risks and Side Effects:

There are no physical or biological risks to participation in the project. Potential risks include discussion of potentially embarrassing or uncomfortable material as well as both authorized and mandated disclosure of information that is potentially harmful or embarrassing. If a Parent Navigator is concerned about the mental health of a parent, he/she will offer the family mental health resources, accessed on the DC-MD-VA (DMV) Perinatal Mental Health Resource Guide publicly available on dchealthcheck.net. If a Parent Navigator is concerned about abuse or safety of a child participating in the study, he/she will consult with the Child and Adolescent Protection Center at CNMC AND notify PIs immediately by telephone. The PIs will be responsible for any further action or reporting.

Measures taken to minimize risk: The study protocol and all related materials including educational materials, scripts, and survey questions will be approved by the institutional review board (IRB) at CN prior to the start of patient recruitment. All efforts will be made to protect the anonymity of participants. Using standard approaches, each participant will be reminded at the beginning of each interview that s/he has the right to refuse to answer any questions without further information or to terminate the interview and withdraw from the study at any time. No identifying information other than a unique study identifier will be used in the surveys. Information used to contact participants for follow-up interviews will be recorded and stored separately from the surveys. Furthermore, to minimize breach of confidentiality, study records will be kept in a single secure location (locked cabinet in a locked room) at CNMC. Consent forms and master study documents that could link the unique identifier to participants will also be kept in locked files. To further ensure data security, all data entry, coding and analyses will be conducted centrally at CNMC. When analyses are actively being conducted, a copy of the data set will be kept on a password-protected machine behind our institution's firewall; this machine will be kept in a locked office to physically limit access. Once analyses have been completed, the data will be removed from the hard drive(s) of any computer(s) used for analysis, and will be stored

solely on CD-ROMs in a secure location. All members of the study team will maintain certification with their IRB of record of their qualification to be involved in human subjects research.

Subject Privacy and Confidentiality:

Study staff will explain the study and answer questions in a private setting in the hospital. A copy of the consent form, explaining the study and its procedures, will be given to the potential participant. Using standard procedures, participants can refuse to participate or terminate participation at any time. Decision to participate or not will not impact their care in any way.

Data Security: To minimize breach of confidentiality, all study records, including consent forms and master study documents, will be kept in a single secure location (locked cabinet in a locked room) at Children's National. No identifying information other than a unique study identifier will be used in the surveys. The baseline and follow up assessment demographic forms will have the participant's basic demographic information and will be stored in a separate file from the surveys in the secure location (locked cabinet in a locked room). Information used to contact participants for follow-up interviews will be recorded and stored separately from the surveys. To further ensure data security, all data entry, coding and analyses will be conducted centrally at CN. All data will be stored on a password-protected hospital network drive or in a secure password-protected program behind our institution's firewall. Once study is finished and all data analysis is complete, the data will be move to long term storage, in accordance with CNMC and PCORI data storage policy. All members of the study team will maintain certification with their IRB of record of their qualification to be involved in human subjects research.

References

1. The NICU Family Support Program. 2014. (Accessed at <https://www.marchofdimes.com/baby/the-nicu-family-support-program.aspx>.)
2. Verma RP, Sridhar S, Spitzer AR. Continuing care of NICU graduates. *Clinical pediatrics* 2003;42:299-315
3. Escobar GJ, Littenberg B, Petitti DB. Outcome among surviving very low birthweight infants: a meta-analysis. *Archives of disease in childhood* 1991;66:204-11.
4. McCormick MC. Has the prevalence of handicapped infants increased with improved survival of the very low birth weight infant? *Clinics in perinatology* 1993;20:263-77.
5. McCormick MC. The outcomes of very low birth weight infants: are we asking the right questions? *Pediatrics* 1997;99:869-76.
6. Aylward GP, Pfeiffer SI, Wright A, Verhulst SJ. Outcome studies of low birth weight infants published in the last decade: a metaanalysis. *The Journal of pediatrics* 1989;115:515-20.
7. Preyde M, Ardal F. Effectiveness of a parent "buddy" program for mothers of very preterm infants in a neonatal intensive care unit. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne* 2003;168:969-73.
8. Willis V. Parenting preemies: a unique program for family support and education after NICU discharge. *Advances in neonatal care : official journal of the National Association of Neonatal Nurses* 2008;8:221-30
9. U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Bureau. *The National Survey of Children with Special Health Care Needs Chartbook 2009-2010*. Rockville, MD: U.S. Department of Health and Human Services; 2013

10. McPherson M, Arango P, Fox H, et al. A new definition of children with special health care needs. *Pediatrics* 1998;102:137-40.
11. The medical home. *Pediatrics* 2002;110:184-6.
12. Homer CJ, Klatka K, Romm D, et al. A review of the evidence for the medical home for children with special health care needs. *Pediatrics* 2008;122:e922-37.