Parent-to-parent Coaching While Awaiting Hospital Discharge With a Child With a Ventilator
Protocol Narrative

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Protocol Narrative
Parent-to-Parent Coaching While Awaiting Hospital Discharge: an empowerment model for home health nurse (HHN) advocacy

Background

Children with invasive mechanical ventilation (iMV) have prolonged index hospital admissions due to delays in home health nursing.[1,2] For children with iMV the index hospitalization (i.e. when a tracheostomy is first placed) is often prolonged by weeks or even months due to non-medical reasons, primarily long waiting times to staff home health nursing.[3-6] Prior studies have demonstrated that the median length of stay (LOS) for these index admissions is many months with outlier LOS of several years. A prior study in the Chicagoland area by Sobotka et al. examined factors impeding hospital discharge for children in a iMV program, and found delayed discharge due to lack of home nursing and protracted parent training.[7]

In other pediatric populations, Black and Hispanic patients have been found to have longer LOS than Non-Hispanic White (NHW) patients. In a large cohort of post-surgical pediatric patients insured by Medicaid, Black children had longer LOS and intensive care unit time that NHW children after controlling for clinical predictors of LOS.[8] Similarly, in chronic disease cohorts including private and public insurance sources, Black and Hispanic children have longer LOS than NHW children.[9] However, to date most studies of LOS for children with iMV are small cohorts at single centers,[2,7] and therefore, it is not known if Black and Hispanic patients with iMV across the US have longer hospitalizations than NHW patients.

Supportive home health nursing services are needed for children with iMV assistance. Children with iMV assistance require the support of home care nursing to be cared for safely at home. In April 2016, the American Thoracic Society (ATS) convened an interdisciplinary Pediatric Chronic Home Invasive Ventilation Workgroup to develop Clinical Practice Guidelines for Pediatric Chronic Home iMV.[10] They recommend an awake and attentive trained caregiver be in the home of a child with iMV at all times, further remarking, “for most families this requires the support of a professional appropriately trained in-home caregiver to allow family caregivers time to sleep, work and maintain a life balance.” Quality home care nursing is essential for family well-being (child medical stability, parental sleep and ability to work outside the home).[11,12] However, gaps exist in essential home nursing services for families.[13] It is not yet known if Black and Hispanic children with iMV across the US receive fewer nursing services than NHW patients.

Homecare is extremely challenging for families, and caregiving results in extraordinary demands on parents, most often mothers.[14-16] Parent-to-parent support models reduce psychological distress, improve parenting self-efficacy, and provide practical solutions.[17-19] Caregiving for children with disabilities results in significant stressors related to daily needs, access to nursing services, parent physical and mental health, and family finances.[20-25] Parents often feel stressed, overwhelmed, and unsupported by community healthcare services.[13,26,27] As a result, parents of children with iMV are generally isolated.[23,28,29] Supportive networks of parents with similar lived experiences can provide essential support.[30,31] These support models utilize social and practical support, problem-solving skills, and empathic understanding. Peer-to-peer support models can enable parents of children with disabilities to flourish and transition from surviving to thriving.[32,33]

In our small cohort of twenty-three children with iMV first transitioning home (NICHD, K23HD097276), Black and Hispanic children had longer index hospitalization that NHW children. Our central hypothesis is that Black and Hispanic children with iMV have (1) longer LOS during index hospitalizations, and once discharged receive (2) fewer home health nursing hours than NHW children. We hypothesize that a parent-to-parent coaching model informed by prior work has the potential to activate families for the advocacy skills needed to build home nursing teams using creative and assertive strategies. This protocol is innovative for its focus on

healthcare utilization in this population through the lens of the framework of racial and ethnic disparities. Our overall objective is to analyze hospital LOS and nursing service receipt in a large population of children with iMV to demonstrate the national need, paired with a pilot a Chicago-wide intervention to impact on existing disparities in care. This protocol will provide pilot data for both national trends and intervention feasibility to support subsequent R-level interventions designed to reduce disparities for Black and Hispanic families.

Parents of children with medical complexity and/or disability have been shown to benefit from parent-to-parent coaching models, and this parents are uniquely qualified to help one another.[17,33] The proven benefits include social support enabling parents not to feel as isolated and alone in their struggles, "sense of sameness," and to meet specific needs the parents themselves identified.[18] We hypothesize that parents of children with iMV will be invested in a program involving parent support because they are typically socially isolated and eager for connection to parents in similar circumstances.

Purpose

The objective of the study is to pilot a parent-to-parent coaching model with experienced family members of children with iMV as parent coaches. Parent coaches will advise parents of children with iMV awaiting hospital discharge on strategies for advocating for home nursing. Parents and parent coaches will meet as needed and engagement will be tailored to parent preference: text messaging, video or phone conferencing, or in-person visiting in the family home or hospital. Points of contact, issues addressed, and time required will be collected as needs assessment data to appropriately size and scale a future intervention. Enrollment and exit assessments will include completion of the Family Empowerment Scale and a brief structured interview about parents' perceived impact and acceptability, which will provide pilot data to inform a future intervention. We hypothesize that parents will gain self-advocacy skills specific to recruiting home health nurses and improve the size of their home nursing workforce through this coaching model.

Methodology:

We will recruit parents whose children are awaiting discharge from a Chicagoland hospital with iMV through a few mechanisms. First, we will partner with the Home Care program of the State of Illinois Division of Specialized Care for Children (DSCC), specifically a newly appointed "staffing support specialist" who is a resource for care coordinators. This DSCC employee will distribute information about the parent-to-parent coaching model to parents awaiting hospital discharge. DSCC staff will share contact information for parents interested in our study with study staff. Study staff will contact the families to further explain the study, complete consent process (over the phone or on the first engagement visit) and enroll families in our study. Enrolled parents will be paired with parent coaches to provide advice on recruiting and maintaining home healthcare teams. We will also recruit through flyers to provider contacts at tertiary and transitional care centers in the Chicagoland area.

Subjects:

The DSCC Home Care Enrollment Manager will identify eligible parents of children with a tracheostomy and ventilator awaiting hospital discharge in Illinois. The child must be enrolled in the DSCC Home Care Program and the parent/legal guardian must have legal custody of the child and plan on living with the child in the home.

30 families will be enrolled in the study.

Recruitment.
The Staffing Support Specialist at DSCC will introduce our parent-to-parent coaching study first to care coordinators for families highlighted by the agency as a hard-to-staff case awaiting hospital discharge. Families who express interest in gathering more information will be contacted by the study team for further information and for study enrollment. Study enrollment activities (consent, enrollment assessment) will occur during over the phone or zoom conference. We will also recruit through flyers to provider contacts at tertiary and transitional care centers in the Chicagoland area

In addition parent liaisons may share IRB approved flyers to private social media groups. If potential participants are interested they will be encouraged to reach out to the study team.

Eligible families will be contacted by a member of the research team and informed consent will be obtained prior to the initial enrollment assessment.

Initial Assessment.
Parents will complete the Family Empowerment Scale (FES), a 34-item scale designed to assess empowerment in parents whose children have emotional disabilities. Our team has reviewed the items and believe it has important parallels for a population of children with iMV who rely upon community-based nursing services. In order to avoid bias, the assessment tools will be administered by a team member not assigned to the family as their dedicated coach. In addition to this parents will complete a demographic survey via REDCap survey which will contain items related to the child's medical conditions and current perceived barriers to discharge.

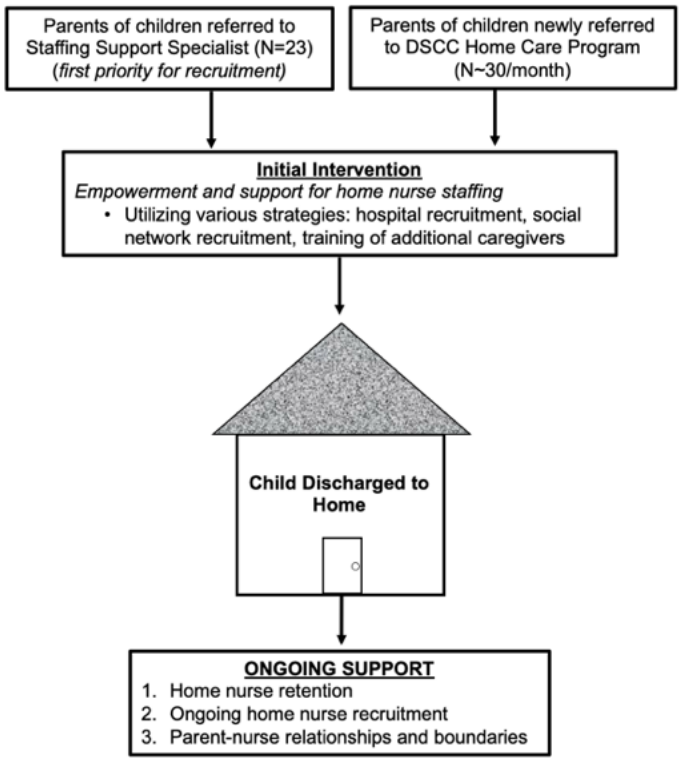
Intervention.
Parents and parent coaches will meet as needed via the family's preferred method. Engagement may include text messaging, phone conferencing, Zoom conferencing, or occasional in-home or hospital visiting as preferred. Points of contact, issues addressed, and time required will be collected as data to scale a future intervention and tailored needs assessment. Coaching sessions will vary based on family desired frequency and location, but may include: on-site in the family home or hospital room, telephone or video conferencing, or asynchronous contacts via email or text messaging. The template for the intervention includes an initial introductory session which is intended to build rapport and orient the parent to our program. This will be offered in person or via phone or zoom call. Subsequent session topics may include: addressing specific needs including topics of interviewing and selecting home health agencies, expectation setting for home based nursing care, recruiting for home health team from inpatient settings, recruiting for home health team from care.com and other professional networks, and recruiting for home health team from personal networks. In this pilot study we are anticipating 6 months of participation. If parents are wishing to exit the study sooner we will route them to the exit assessment as needed.

Exit Assessment.
All study participants will be offered an exit interview 1 month after they have been discharged from the hospital or 1 month before the end of the study. A research team member other than the coach will contact families to refer to additional support services as needed. A team member will repeat the FES and components of the demographic survey that have changed and complete a brief structured interview about family perceived impact and acceptability to inform a future intervention.

Parent Exit Interviews:

Interviews will occur in person or over Zoom with parents of children with iMV to understand their perceived impact of the parent-to-parent coaching program. These responses will also be stored in REDCap.

Figure 3. Parent-to-Parent Intervention to Support Parents of Children with iMV



Duration:

Participants will be involved for about 6 months or until they feel that they no longer need the parent-to-parent support.

Parents will participate in the following contact attempts:

- Introductions and rapport building which will include a demographic survey with a needs assessment, and the Family Empowerment Scale (FES)
- A series of coaching points which may include some or all of the following topics
    - Interviewing and selecting a home health agency
    - Expectation setting for home based nursing care
    - Tips for finding home health professionals from inpatient nursing
    - Tips for using care.com and other settings to find potential home health team members to staff their cases
    - Tips for using personal networks to find and recruit home health team members
    - Assistance with contacting DSCC and/or the home health nursing agency
- An exit interview assessment including the FES and components of the demographic survey that may have changed

Location:

Study enrollment and all touch points will take place either in person, or over zoom video teleconferencing, phone call, or text exchange.

Special Precautions:

None

Placebo/Use of Controls:
None

Analysis:
Feasibility will be determined by recruitment and retention rates. Parent coaches will collect data on number of touchpoints with families, issues addressed, and time required.

Potential Risks and Benefits:
Informed Consent
The DSCC Staffing Support Specialist will briefly describe the study to the child's guardian and, if interested, request permission for Dr. Sobotka's research team to contact the parent. If more than one parent or guardian is interested in participating, and they meet the eligibility criteria, each parent/guardian will be asked to provide consent. After a conversation describing the study procedures, study team members will obtain consent. During the consent discussion parent subjects will be reminded that they may stop the study at any time.

Protection Against Risk
Survey and interview questions will ask parents to reflect upon their experiences receiving the parent coaching. Oftentimes the circumstances which surround a child's medical fragility are traumatic or unexpected. In the course of the parent-to-parent coaching and engagements with the family there is the possibility that there may be an incidental finding of clinically-significant depression or anxiety. If this occurs, Dr. Sobotka, the PI, will further assess the parent/guardian for level of symptom severity and refer to outpatient mental health services or emergency mental health services as she determines appropriate for level of risk. The Division of Specialized Care for Children has embedded into its home care program a high number of trained mental health professionals (social workers) employed as care coordinators. Additionally, financial support for mental health services for parents is a core component of DSCC's offered benefits for children in the home care program. As needed, and with parent permission, Dr. Sobotka will reach out to DSCC care coordinators for additional mental health support from DSCC or via external referrals for parents enrolled in her study.

Upon entering the study, participants will be assigned a study identification number which will be used in record keeping and analysis. All personally identifying information will be stored separate from study records. All subject materials will be kept in a locked office and on encrypted, password-protected University-owned computers. Survey data will be stored on password-protected computers accessed only by research staff. The coded document linking the study code to participants names will be stored in an encrypted file on encrypted computers.

The study results will be kept in locked offices and on encrypted computers by the research team indefinitely. Correspondence regarding family enrollment will be between DSCC Care Coordinators and University of Chicago research staff using secure, encrypted email and telephone calls.

On site in the family home, data collection will be conducted using secure devices (research iPads). Communication between research staff and participants will occur via emails and telephone calls to University of Chicago email accounts and secure office lines as well as text messages.

Confidentiality:
This is a single-site study. Confidentiality of subjects will be maintained and PHI will be securely

maintained at the University of Chicago. Data obtained from the research remains confidential and subjects will not be identified in any resulting publication. Study records will include responses to the Family Empowerment Scale (FES), measures of parent engagement in the coaching model, as well as demographic data collected using the secure University of Chicago Research Electronic Data Capture (REDCap) system. REDCap is a web-based application developed by Vanderbilt University to capture data for clinical research and to create databases, surveys, and projects.

Parent-to-parent coaching sessions will take place in a quiet location in person per family preference (family home, hospital room) or over telephone or Zoom video conferencing hosted by password-protected University of Chicago accounts. At the conclusion of the study a team member other than the parent coach will repeat the FES and complete a brief structured interview about family perceived impact of the parent-to-parent coaching program and acceptability to inform a future intervention.

Study records will be maintained by the PI and study team members. Data will be reviewed on a regular basis by the study team to ensure validity and compliance. All subject materials will be kept in a locked office and on password protected computers.

Potential Benefits

The potential benefits from participating in the intervention include a positive emotional impact of meeting a parent coach who has also cared for a child with a tracheostomy and ventilator and managed home health teams, and potential improved access to home care nursing through creative strategies shared by the parent coaches. The identified risks are reasonable because they are minimal and are outweighed by the benefit of providing valuable insight and subject matter knowledge.

Payment to Subjects:

Participants will be given a $25 gift card when they enroll in the study and a $25 gift card at the completion of their involvement as a thank you for participating.

Informed Consent Process:

We will obtain written consent from the participants in the study via either physical consent form collected in person or REDCap e-consent collected via zoom or telephone consent conversation.

Special Precautions:

Not applicable.

Experimental controls and use of placebos:

Not applicable.

Monitoring of Safety:

No formal data safety and monitoring board will be utilized. However, if there is a data breach at UChicago, the study staff will report the event to the IRB and notify the HIPAA office within 24 hours.

Notification of primary physician:

Not applicable.

Anticipated Coordination:

Not applicable.

Pregnancy Testing:

Not applicable

Exclusion of participants (women, children, or minorities):

The only groups who will be excluded will be wards of the state.

Medication Infusion:

Not applicable

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