STUDY PROTOCOL, INCLUDING STATISTICAL ANALYSIS PLAN (SAP)

Official Title: Nurse-to-Family Telehealth for Pediatric Transfers: A Randomized Controlled Pilot Trial

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Objectives

Our central hypothesis is that telehealth use to connect a care team member from the receiving hospital virtually with the child's parents may increase family-centeredness of care, reduce parent stress, and improve triage appropriateness. A pilot study is needed to explore the feasibility of conducting a nurse-to-family telehealth trial. We therefore aim to test the feasibility of conducting a parallel cluster randomized trial comparing nurse-to-family telehealth communication to usual care for pediatric transfers. Feasibility will be assessed by protocol assignment adherence, fidelity, and survey response rates.

Eligibility

Inclusion: Eligible patients will be children aged eight days to less than or equal to 18 years who present to a participating community hospital emergency department (ED), are accepted for inter-facility transfer, are assigned to arrive as a direct admission (i.e., ED-to-inpatient) to one of three eligible hospital units, and have an adult parent or guardian at the bedside with English language preference. The eligible units include the pediatric intensive care unit (ICU) and two pediatric acute care units.

Exclusion: Transfer consultations for children less than 8 days of age and those destined for the neonatal ICU will be excluded, since neonatal patients have unique transfer patterns. Children who are transferred from ED-to-ED will be excluded to prioritize feasibility and first test the intervention in a homogeneous context. This trial excludes those who do not have a parent with English language preference, because we will use an existing telehealth platform that is only available in English. We will first pilot test this intervention before adapting the platform's family-facing interface into additional languages.

All eligible children will be enrolled in the study. This research has a waiver of consent for the intervention, because telehealth visits are an existing clinical resource that can be used for all transferring patients. The decision to use telehealth in this trial will be encouraged in the intervention arm but will remain optional; no nurse or parent will be required to use telehealth. The parent survey that will be used for data collection of exploratory outcomes will have elements of informed consent before the survey questions.

Exploratory Outcomes

In addition to testing feasibility objectives (**Table 1**), we will measure subject-level exploratory outcomes data to test feasibility of data collection and to obtain effect size estimates. Exploratory outcomes include family-centered care, family experience, parent acute stress, parent distress, and change in level of care. Family-centered care of the community ED encounter will be assessed using the ED Family-Centered Care Experience (ED-FACCE) survey. Family experience will be measured using the two items measuring overall experience from the ED Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. Parent acute stress and distress will be assessed using the Emotional Distress: Anxiety measure. Change in level of care will be measured at two timepoints: (1) between initial unit assignment and post-transfer arrival and (2) between post-transfer arrival until 12 hours after arrival. Change in level of care will be defined as switching from an acute care unit or service to an intensive care unit or service, and vice versa.

Table 1: Feasibility objectives

Feasibility objective	Indicator	Criteria for success
(1) Protocol assignment adherence	Proportion of eligible patients for whom the protocol assignment (telehealth initiated versus usual care) is followed	Adherence will be 75% or greater
(2) Fidelity: timing of delivery	Whether the telehealth connection is initiated prior to the patients' arrival to the children's hospital	Fidelity will be 75% or greater
(3) Survey response rate	Survey response rates for each survey-derived outcome	Survey response rates will be 75% or greater

Procedures Involved

Randomization: The unit of randomization will be the community hospital, which decreases contamination in comparison to randomization at the patient level (under which each ED would have simultaneous telehealth visits and usual care). We will use constrained randomization to better balance the intervention and control arms with respect to ED-to-children's hospital distance and pediatric transfer volume. Distance will be categorized into less than 21 miles, 21-50 miles, and more than 50 miles. Transfer volume will be categorized into less than 21, 21-60, and more than 60 annual pediatric transfers that arrive as direct admissions to a pediatric ICU or pediatric acute care unit.

Intervention: Per standard procedures, after a children's hospital physician accepts a patient for transfer, the transferring patient is assigned a hospital unit by the bed control nurse. The charge nurse will accept or deny the patient to their unit. Upon accepting a patient to their unit, this charge nurse will determine whether the transferring patient meets trial eligibility criteria and is transferring from an intervention-arm ED site. Upon confirmation that the patient is eligible to receive a nurse-to-family telehealth visit, the charge nurse will call by telephone the community hospital ED and ask the bedside nurse to offer a telehealth visit to the patient's parent(s). If the parents would like to have a nurse-to-family telehealth visit, the ED nurse will give the parent's cell phone number or email address to the children's hospital charge nurse.

The children's hospital charge nurse will then use their video-enabled computer to launch a telehealth visit using the secure telehealth application called ExtendedCare. The ExtendedCare platform meets Health Insurance Portability and Accountability Act security rules and launches from the patient's electronic health record. From within this telehealth visit, the charge nurse will send an electronic message (e.g. via text or email) to the parent and wait for the parent to join the visit (establish a secure videoconference). The message to the parent includes a link that can be clicked to open a browser that allows the parent to join the telehealth visit. The parent does not need to download or use any application or program.

Charge nurses are instructed to initiate the telehealth visit prior to the patient leaving the community hospital ED and to wait at least five minutes for the parent to join the telehealth connection. Charge nurses are also instructed that the content of the discussion during the visit is intended to prepare the family and charge nurse for the transfer process and the patient's arrival. This workflow requires that the parent has a smart phone with access to text messaging or email. If a parent does not have a smart phone with access to text or email but would like to speak with the charge nurse, a phone call will be offered instead. Other interventions related to parent-provider communication that are delivered prior to the arrival at the post-transfer hospital will be prohibited during the trial.

Control: Subjects presenting to control-arm ED sites will receive usual care. These subjects will transfer to the children's hospital without the parent communicating with the charge nurse. The charge nurse will not have direct communication with anyone from the ED. The charge nurse will communicate with the children's hospital bed control nurse and review the written documentation about the patient in the electronic health record.

Data collection: Data collection for the feasibility objectives and exploratory outcomes will include chart review of the electronic health record and parent surveys. Parent surveys will be distributed to one parent per enrolled patient. Parent respondents will include only English-proficient individuals who were with their child during the ED visit. For children who had more than one parent at their ED bedside, we will let the parents select the single respondent. Eligible parents will receive the family-centered care, experience, and anxiety instruments 0-3 days after the ED encounter. Parent distress will be measured at 30 days from the ED encounter. Surveys not completed within 21 days of distribution will be considered non-response. Participants will receive a $25 gift card for each survey packet that they return. Parents completing both survey packets will therefore receive a total of $50 in gift cards.

Data collection for the exploratory outcome change in level of care will use chart review. Electronic health record data will be used to abstract patient demographics (age, race, ethnicity, sex, insurance, California Healthy Places Index) and utilization variables (admitting service, length of stay, disposition). Demographic characteristics of family caregivers (age, race, ethnicity, gender, education, smart phone access, digital literacy score) will be collected in the survey packets.

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For feasibility objectives, proportions with 95% CI will be calculated for protocol assignment adherence, fidelity, and survey response rates to determine if each of the feasibility objectives is met. For the exploratory

outcomes, analyses will be descriptive, designed to provide effect size estimates with 95% CI. To account for the cluster randomized design, we will use analysis methods for clustered data when estimating confidence intervals, treating ED sites as clusters.

Although we do not anticipate strong cluster effects for the feasibility objective outcomes, we recognize that our confidence intervals will be inflated both by the modest intracluster correlation and by the use of critical values from t-distributions with only 5 or 2 degrees of freedom, depending on whether the objective concerns patients from all 6 sites (objectives 1 and 3) or from just the 3 intervention sites (objective 2). Hence, we anticipate that our actual sample size will perform as effectively as a sample size one half smaller for objectives 1 and 3 and as 60% smaller for objective 2. For feasibility outcomes, an actual sample size of 120 will be sufficient to estimate proportions with error margins (i.e., half-width of 95% CI) of ≤12.7 percentage points for the primary feasibility objective (objective 1) and for objective 3, which involve the full sample. For objective 2, we anticipate fidelity testing on an actual sample of size 45, which will result in error margins no greater than 23.0 percentage points. This pilot trial is not powered to determine the relative benefit of telehealth versus usual care, as that important question will be answered in a future efficacy trial. The chosen sample size of 120 patient encounters prioritizes feasibility over power.