Evaluating the Value of Telehealth for Care of Children With Medical Complexity
Clinicaltrials.gov Identifier: NCT02849938
Unique Protocol ID: CCCMCTeleMed

Study Protocol and Statistical Analysis Plan
Last Revised: September 29, 2016

Participants

This study was designed as a single center, randomized, non-blinded pilot study. Sample size was determined by number of eligible patients enrolled in the Coordinated Care for Children with Medical Complexity (CCCMC) program at our institution as well as number of devices that were available for the pilot. Inclusion criteria included: patients aged 1 month to 18 years, currently enrolled in the CCCMC program; parent consent; at least one English-speaking parent; and in-home Wi-Fi connectivity. Children enrolled in the CCCMC program met the following criteria: 3 or more body systems requiring active management; technology dependent or full support to complete activities of daily living; and moderate or severe neuromotor delays, or intellectual disability. Children were excluded from this pilot study if caregivers expressed an inability to comply with study requirements. Participants were randomized 1.5:1 with stratification based on tracheostomy status to control group or intervention group (Research Randomizer, Urbaniak). This stratification was done to attempt to balance patient contact between the groups based on the assumption that patients with tracheostomies may require more frequent contact with the CCCMC team. Clinicians in the CCCMC program included a pediatrician and pediatric nurse practitioner. This study and subsequent revision was approved by the Advocate Health Care Institutional Review Board and registered at ClinicalTrials.gov (Identifier: NCT02849938).

Telehealth Device

The selected telehealth device (TytoHome[TM]) is an FDA-approved, handheld, mobile device designed for capture and transmission of ear, throat, and skin images, heart and lung auscultations including heart rate detection, and temperature data taken by infrared transdermal thermometer. The device required pairing with an iOS tablet (Apple iPad mini 4) for transmission via wireless network for live-interactive clinician connection. Caregivers used the telehealth device to perform non-invasive medical examinations in the home for remote view by a clinician. TytoCare[TM] provided the telehealth devices and the iPad minis that were used in the pilot.

Procedure

Enrolled parent caregivers provided informed consent during a home visit for study initiation. For those in the intervention group, members of the TytoCare[TM] team were present along with study team to explain the use of the telehealth device and iPad mini; set up the components and connect them to in-home Wi-Fi; and answer any questions. The home was assessed for adequate internet connectivity and supplemental connectivity was provided by TytoCare[TM] if needed.

All caregivers were instructed to contact their clinician by telephone or email as usual when they had any health concerns. If an exam was deemed necessary by the clinician, patients in the control group were referred for an in person encounter, whereas caregivers of patients in the intervention group were directed to connect the telehealth device if appropriate. During a telehealth visit, the clinician conducted a 2-way, live, interactive

audio/video visit with the patient. If clinically indicated the clinician would direct the caregiver to use the telehealth device to provide temperature, lung sounds, heart sounds, oropharyngeal exam, skin exam and/or ear exam. Regardless of the group, the clinician would base direction for necessary treatment, referral to an ED, clinic visit or hospitalization based on available data. In addition, telehealth visits were scheduled in advance for routine care if indicated such as for post-discharge care, follow-up for a particular concern, or to maintain familiarity with the telehealth device (technical practice).

Data Collection

The length of the study observation period was increased from 3 to 4 months due to technology issues that were encountered and managed during the first month of the study (termed "technical month"). Data collection included subject demographics, encounter details (outpatient clinic visits, ED visits, and hospitalizations) that were routinely collected as a part of the CCCMC program, as well as caregiver and clinician surveys, which used a 4-point Likert response scale. All caregivers answered questions about CCCMC program satisfaction, and those in the intervention group answered additional questions about their comfort using the device. Caregivers were emailed a link to the online survey once a month during the study period. Surveys not completed online were conducted over the phone by a member of the study team who did not participate in patient care. Clinicians completed an online survey for each encounter in which they would have liked to complete a telemedicine visit regardless of child's group assignment. They answered general satisfaction questions as well as demographic, feasibility, and

usability questions. Questions on the feasibility and usability of the telehealth device addressed the success of device connectivity, as well as the transmission of real-time images, temperature, and sound. Other questions asked about potential or actual changes in patient management because of the telehealth device. Specific measures to address each study outcome can be found in Table 1.

Analysis

Descriptive statistics were used to summarize data with absolute and relative frequencies for categorical variables and means and standard deviations (SD) for continuous variables. Feasibility and usability of the device as determined from survey responses and reported as median and interquartile range (IQR). Continuous variables were examined using independent groups Student's t-test or the Mann-Whitney U test depending upon normality of data. Dichotomous variables were examined using Chi-square or Fisher exact tests. Data are reported for the first technical month and subsequent 3-month observation period separately.

The impact of device utilization was evaluated by measuring the total number of visits per patient by type (outpatient visits of low, moderate, and high complexity; ED visit without subsequent admission, general pediatric ward days, pediatric intensive care unit days) as determined via chart review. To adjust for the difference in sample size per group, the number of hospitalization days, acute office visits, and ED visits were reported descriptively as a *visit rate* calculated as the number of visits or hospital days/patient study months (number of patients in the group x number of study months). Four months of data were used for the calculation because the control group did not have any

hospitalizations during the technical month. The Kaplan-Meier method was used to estimate the proportion of each group that did not have any hospitalizations during the study period. A statistical comparison of the survival distribution was not conducted because the Kaplan-Meier method does not account for repeated episodes such as patients with more than one hospitalization.

A negative binomial regression model with Generalized Estimating Equations to handle repeated measurements was used to test the difference in hospital length of stay between groups. Model results were reported as regression coefficients, 95% Wald confidence intervals and p values. The negative binomial regression model was appropriate for this analysis, as the distribution of the outcome had greater variability than expected under a Poisson distribution. The sample mean of the outcome (4.3) was substantially smaller than its variance (102.3). Regression models were not tested for the number of acute office or ED visits because the incidence rate was too small for the inferential statistic. Analyses were conducted using SPSS (version 22.0) (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). For all analyses, a p value < 0.05 was considered statistically significant.

Direct cost for each encounter was obtained from our institution's financial accounting system (EPSi), which was used to calculate direct costs per study group and encounter type (not including overhead costs such as cost of the telehealth device or connectivity). For the intervention group, a telemedicine visit was equated to a Level 4 return encounter in the outpatient setting. Direct cost savings were calculated as the absolute difference between the two study groups. To adjust for the difference in group sample size, the

encounter direct cost was multiplied by the visit rate and the adjusted cost rates were described for each group. Potential cost savings were calculated using clinician input on the visit types that were likely prevented as a result of the telemedicine device.