Primary Care Program Providing Inpatient Consultations for Children with Medical Complexity: a Pilot Randomized Quality Improvement Trial

BACKGROUND AND RATIONALE

Comprehensive care (**CC**) provided in the High-Risk Children's Clinic (**HRCC**) at The University of Texas at Houston (UTH) McGovern Medical School involves care for acute and chronic conditions from a team of ethnically diverse pediatricians and nurse practitioners who are knowledgeable about each patient and highly trained and experienced in treating medically complex and fragile children. This clinic serves as a novel medical home where both primary and specialty services are provided in the same place at the same visit. Acute problems presenting before 4 pm are seen the same day or if they occur over the weekend, on Monday morning. All parents have the cell phone number to directly reach one of the primary care clinicians at all hours. Multiple measures are used to promote and ensure the highest quality of care such as daily checks of emergency department and hospital logs to ensure prompt follow-up and coordination of care, weekly HRCC provider team meetings to review the care provided before every ED visit and hospitalization, high priority given to minimizing unnecessary ED visits and hospitalizations, and a relatively low patient-to-staff ratio of no greater than 100 (to allow for longer clinic visits, more telephone calls and e-mails, and extensive quality improvement measures).

Comprehensive care undoubtedly increases access to high-quality healthcare for high-risk disadvantaged chronically ill children. The findings of our previous randomized trial of comprehensive care vs. usual care that were given accelerated publication in JAMA (2014) have attracted national attention as the best evidence to date supporting medical homes to reduce either adverse outcomes or costs. [1] Comprehensive care resulted in major benefits (ED visits, admissions, hospital days, and pediatric ICU admissions and days were all reduced by 47-69%) and savings from the health system perspective were >$10,000/child-year.[1] Indeed, the improvements in outcomes and reduction in costs exceed those previously reported in prior studies of medical homes for patients of any age or condition. [1-3] Despite these demonstrated benefits, high-risk patients seen in the High-Risk Children's Clinic still experience high rates of

morbidity and often require hospitalization for treatment of acute exacerbations of their underlying chronic conditions. In 2015, a total of 100 HRCC patients experienced 175 admissions at Children's Memorial Hermann Hospital (**CMHH**) - that serves as the UTH tertiary teaching hospital - for a mean length of stay of 7.1 days. As a result, a pilot quality improvement (**QI**) trial will be conducted to assess the impact of offering inpatient consultation (**IC**) by the HRCC providers at CMHH to further optimize coordination and integration of inpatient and outpatient care and reduce total hospital days per child-year for the HRCC patients.

Hypotheses:

Primary Hypothesis: We hypothesize that relative to usual inpatient care, the inpatient consultation service will decrease the total number of hospital days per child-year.

Secondary Hypotheses: We hypothesize that relative to usual inpatient care, the inpatient consultation service will:

1. Be cost-effective by either decreasing the number of hospital days per child-year without increasing health system costs, decreasing health system costs without increasing hospital days, or decreasing both.
2. Decrease the total number of PICU days per child-year at CMHH.
3. Decrease the 30-day ER visit rate following CMHH discharge.
4. Decrease the 30-day re-admission rate following CMHH discharge.
5. Increase parent/caregiver satisfaction as measured by pre-selected Hospital CAHPS survey questions, which will be administered to the parent/caregiver 5-10 days after discharge from the CMHH by study personnel who are not involved with the clinical care of patients.[4]
6. Increase the rate of inpatient consultations with the CMHH inpatient physician team during admission - i.e. face-to-face consultations, non-face-to-face consultations, or a phone call to the inpatient physician team.

7. Increase the rate of follow-up phone calls from HRCC providers to parents/caregivers within 36 hours after discharge from CMHH.
8. Increasing the rate of follow-up clinic visits in the High-Risk Children's Clinic within 5-10 days after discharge from CMHH.
9. Decrease the rate of serious illnesses (death, hospitalization > 7 days, or PICU admission) during the study period.

METHODS

Setting. The High-Risk Children's Clinic of the UTH is a patient-centered medical home for CMC. Children who require hospital care in our center are usually treated at Children's Memorial Hermann Hospital (CMHH), a private institution adjacent to our medical school that serves as the UTH tertiary teaching hospital.

Inclusion/Exclusion criteria. HRCC patients who require admission to CMHH will be included in the pilot trial. HRCC patients ≥ 18 years of age at study initiation will be excluded from the pilot trial and so will those with a Do-Not-Resuscitate (DNR) order, unrepaired congenital heart disease, active cancer, mitochondrial disorder, or seen in the HRCC clinic solely for compassionate care.

Design. All eligible HRCC patients will be randomized to either comprehensive care with usual inpatient care or comprehensive care augmented with inpatient consultation utilizing a computer-generated algorithm with variable block sizes. Patients will be stratified by assigned provider and baseline clinical risk (high risk if ≤ expected median risk or very high risk if > expected median risk, as judged by the clinic's medical director [R. Mosquera] based on diagnoses and prior clinical course).

Treatment Groups.

Comprehensive Care with Usual Inpatient Care. Includes comprehensive outpatient care in the

HRCC and usual inpatient care provided by the CMHH hospital inpatient team (residents, fellows, and attending faculty physicians) with usual occasional communication with HRCC providers. This care will not be modified by the study protocol.

Comprehensive care Augmented with Inpatient Consultation. Includes comprehensive outpatient care in the HRCC and inpatient consultation by HRCC providers during admissions at CMHH. The HRCC providers will review the inpatient care plan and make treatment and discharge recommendations to the hospital inpatient team with a focus on coordination and integration of inpatient and outpatient care. The inpatient consultations will consist of either face-to-face consultations, non-face-to-face consultations, or a phone call to the inpatient physicians at a minimum on admission and at discharge, including during observation stays.

Enrollment period. Enrollment will occur between October 3, 2016 and October 2, 2019 and outcome evaluations will continue through either October 2, 2017 or 30 days after discharge from last admission by October 2, 2017 (whichever comes later).

Data Collection and Management. Research Electronic Data Capture (REDCap) software will be utilized to collect and manage predefined study variable data. REDCap is a secure, web-based application designed to support electronic data capture for research studies providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

Cost Assessment. The incremental costs of comprehensive care with inpatient consultation vs. comprehensive care with usual inpatient care will be assessed from the health system perspective. Hospital costs for inpatient services will be obtained from the Memorial Hermann Hospital institutional accounting system. Costs for professional services provided during CMHH hospitalizations will be assessed based on Relative Value Units (RVUs) using UT Health claims data. The costs for hospitalizations occurring outside our center will be imputed based on the mean costs for a hospital day at CMHH observed in our sample. Clinic costs for comprehensive care will be estimated using the total expenditures of the High-Risk Children's Clinic. Costs for

outpatient services provided in our center but outside the HRCC (such as diagnostic imaging tests) will be calculated using the standard RVU-based method. The costs for the comprehensive care with inpatient consultation group will be augmented by the HRCC personnel time cost for providing inpatient consultation based on the HRCC staff salary and fringe data. All costs will be inflated to the year of analysis based on the Consumer Price Index for medical services.[5] The investigators will consider the program to be highly cost-effective if it reduces the total number of hospital days per child-year without increasing costs, reduces costs without increasing the total number of hospital days per child-year, or reduces both.

Statistical and Economic Analyses. All intent-to-treat statistical and economic analyses will be performed using multilevel generalized estimating equations (GEE) models with exchangeable correlation to account for family clustering, robust standard errors, and log link. The economic analyses will be performed according to current standards for such analyses.[6-9] Differences in hospital days and costs between treatment groups will be assessed using GEE models with gamma distribution. Rates of secondary outcomes will be assessed using binomial GEE models, whereas total number of secondary outcomes will be assessed with negative binomial GEE models. All the models will be adjusted for the trial's stratifying variables (assigned provider and baseline clinical risk) and for within-family correlation. In this small pilot study, some treatment effects that would be considered important by family members and clinicians (reduced hospital days) may not be statistically significant. As a result, Bayesian analyses will be performed to estimate the probability of a benefit of a given magnitude and evaluate whether further study is justified. Neutral and skeptical priors will be used. The study will also allow us to obtain the experience and data needed to refine the process for providing inpatient consultations for high-risk chronically ill children. All frequentist statistical analyses will be performed using Stata version 13.1 (Stata Corp, College Station, TX). The Bayesian model will be implemented using OpenBUGS.

Stopping Rules. We plan to enroll patients in the pilot trial for 3 years. However, under predefined stopping rules, enrollment will cease if Bayesian analyses performed at the end of the first year identifies a 80% or greater probability that inpatient consultation reduces the total number of hospital days per child-year relative to usual inpatient care. This analysis will

use a neutral prior centered at RR of 1.0 with 95% prior interval of 0.3-3.3.

Ethics and Trial Registration. The Committee for the Protection of Human Subjects (CPHS) at The University of Texas Health Science Center at Houston (UTHealth) determined that this Quality Improvement (QI) Project does not require Institutional Review Board (IRB) approval. This study is registered at ClinicalTrials.org (ID: NCT02870387).

References

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