Communication to Improve Shared-Decision Making in Attention-Deficit/Hyperactivity Disorder (ADHD)

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Analytic and Statistical Approaches

Aim #1: To determine differences in the comparative effectiveness of the tier 1 vs. the tier 2 intervention for children with ADHD, we followed the standard of an intention-to-treat repeated measures longitudinal analysis that modeled baseline, 3-month, 6-month, and 9-month measurements as outcomes; allowed for correlation of measures within child over time; used all data collected; allowed for and adjusted for dropout or non-adherence to assigned treatment; adjusted for differences in patient characteristics not balanced by randomization; clustered by practice site, and permitted continuous, count, and binary outcomes. To check for randomization of patients, patient characteristics were compared between the groups in the tier 1 and tier 2 interventions using Chi-square tests for categorical variables, and t- tests/Wilcoxon rank sum tests for continuous characteristics. To assess bivariate associations between patients in the care manager and portal group vs. portal alone and outcomes, t-tests were utilized for ADHD symptoms, parent and child PRO measures, and goal attainment. These analyses were stratified by timepoint. For the primary outcomes of ADHD symptoms, and secondary goal attainment and PRO measures, linear mixed effects and marginal (GEE) models were implemented. For binary outcomes of the proportion of children with normalized symptoms and goals attained, marginal models (GEE) were implemented and weighted as needed for any dropout.[96,97] As these models have different assumptions, using both allowed us to confirm that assumptions were met. We followed usual guidelines for reporting results (CONSORT),[98] and reported all outcomes in interaction of intervention status and time in days was included. Season in which the survey was completed (Summer: June 16-Sept 15, Fall: Sept 16-Dec 15, Winter: Dec 16-Mar15, Spring: Mar 15-June 15) was also included to account for the potential influence of seasonality on outcomes.,[99,100] as participants were enrolled at different times of the year. Models included adjustments for child age (5-7, 8-12 years), child gender, child race/ethnicity (white, black, Hispanic, other), free/reduced school lunch, metropolitan status (urban, suburban), child SSI status, parent education level ($\leq$ high school, some college, college degree), school type (public, private, charter), and ADHD medication status. Additionally, in order to account for clustering, clinic site was included in each model as a random effect.

We conducted sensitivity analyses to examine the impact of preference and treatment intensity on the main outcome of ADHD symptoms. We stratified tier 2 participants by intervention dosage (frequency of interaction with the portal/care manager): 0-1 sessions, 2 sessions, or 3 or more sessions. We compared differences in ADHD symptom score changes over time by intervention dosage using a linear mixed effects model that adjusted for seasonality.

Aim #2: We originally proposed to assess whether family engagement, treatment initiation and adherence were mediators of intervention treatment effects: This analysis proposed to focus on the role of engagement and treatment initiation at 3 months or adherence at 6 and 9 months as mediators of the effect of the intervention on the study outcomes. Since none of the primary or secondary outcome measures were different between groups, we elected not to proceed with formal tests of mediation. Instead, we assessed for differences in family engagement and treatment initiation and adherence between groups. For each of the above sets of potential mediators, we report distributions by case/control as assess bivariate differences via t-tests or contingency tables/Chi-square analyses where appropriate.

In order to assess family engagement, a series of items were created from review of the literature and prior instruments in other fields. We utilized confirmatory factor analyses to find distinct domains for which each item loading was greater than 0.7. Our first round of analyses resulted in 3 factors: patient/family centered care, communication, and understanding. Upon presentation to the study team, there were several items that were dropped from the initial domains, but additional items resonated with the team as important concepts in which the intervention was focused. Thus, the study team came to consensus on items that should be included. These items represented four conceptual domains. The 4-factor structure was supported in confirmatory factor analyses. While the patient/family centered care and understanding domains remained the same, the original communication domain was split into two factors, resulting in the following domains: care team accessibility; patient and family-centered care; communication among members of the care team, and understanding of ADHD. To compare patients in the tier 1 and tier 2 groups by engagement

status, we utilized t-tests for each of the four domains separately. Further, linear mixed effects models were implemented for each engagement domain as the outcome, with intervention status and season as covariates clustering for clinic site. We further assessed for item responsiveness using item response methods.

We explored treatment initiation and adherence via the services assessment for children and adolescents (SACA) and medication status.[95] On the SACA, patients reported service use ever, as well as service use within the past 9 months. Categorizations include any service use, ambulatory service use (any community mental health or outpatient clinic, private professional, or in-home provider), and overnight stay (psychiatric or medical unit, residential treatment center, group home, or foster home). Differences between intervention groups and treatment initiation were assessed via Chi-square tests. In addition, treatment initiation and adherence were assessed via medication status throughout the study period. At baseline and 3, 6, and 9 month follow up surveys, participants were asked as to whether their child was on or off medication. If data was missing for a particular timepoint, we utilized medication status within the EHR if available.

Aim #3: To explore individual, family, and community factors that moderate treatment effects, the same longitudinal data models supported estimates of effect modification by means of 3-way interaction terms of time-by-treatment-by effect modifier as well as subgroup analyses. Factors of importance explored in this aim included parent education level (high school vs. less than high school), race/ethnicity, medication status, and neighborhood variables (median income, metropolitan status). To obtain the community level variables, each participant was geocoded via street address, city and ZIP code. American Community Survey Census tract level information including median income, percent high school graduation, population density, and percent poverty were linked to participant tracts. Urbanicity was defined as home residence in Philadelphia County (urban) vs suburban county. Bivariate differences between intervention status and the above factors were assessed utilizing Chi-square tests for categorical characteristics, and t-tests/Wilcoxon rank sum tests for continuous characteristics.

Moderation models and stratified models were conducted separately for each

outcome, following the same modeling strategy in Aim 1 with GEE (marginal) models accounting for clinic site and seasonality.