Title: Engagement and Recruitment in the MOBILITY (Metformin for Overweight and OBese chILdren with bipolar spectrum disorders Treated with second-generation antispsYchotics) study

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Methodological Question Being Addressed: Methods to improve clinician and patient/family engagement and recruitment in a pragmatic clinical trial.

Introduction: Second generation antipsychotics (SGAs) are effective for treatment of bipolar spectrum disorders. However, a common side effect is weight gain, which may lead to medication non-adherence. Metformin (MET) has been shown to mitigate weight gain associated with SGAs in clinical trials, but data on widespread use of MET in care-as-usual settings is lacking. MOBILITY (Metformin for Overweight and OBese chILdren with bipolar spectrum disorders Treated with second-generation antispsYchotics) is multi-site, randomized, pragmatic clinical trial (PCT) to assess the comparative effectiveness of MET plus simple healthy lifestyle intervention (LIFE) vs. LIFE alone on patient-centered outcomes. Given its PCT design, this trial offers unique methodological problems and solutions for engaging clinicians, patients, and families in research in real-world setting.

Methods: Novel approaches were utilized to engage and recruit institutions, clinicians, and patient/families in the PCT design of the MOBILITY trial. Issues unique to sites provided opportunities to address clinician engagement and improve general recruitment as well as enhance enrollment for ethnic minorities, SGA treatment naïve patients, those transitioning from inpatient to outpatient settings, and those transitioning into adult care.

Results: Select sites were able to recruit up to three new patients per month. A variety of techniques were effective in enhancing clinician engagement. Early communication and buy in with stakeholders including institutional leaders and clinician champions to serve as change agents was integral to successful site start-up and continual recruitment efforts. The following methods were successful in enhancing and encouraging clinician involvement: providing supported clinical time for required research training, one to one direct electronic or personal communication with each clinician by the research team, and flexibility around clinician schedules. In addition, research staff screened schedules weekly for potential patients for each clinician and communicated with providers about patient suitability for the study. Patient and family recruitment was enhanced through education regarding patient-centered outcomes research, an emphasis on flexibility, and personal engagement with their individual

providers. To ensure optimal time for patient/clinician visits, patients were asked by to arrive 15 minutes before each appointment to allow time for research related activities with research staff. Research activities (excluding informed consent which was always obtained before the first study visit) were conducted before, during, and after clinical visits to ensure that clinicians could conduct their regular clinical duties.

Conclusions: Novel approaches in a multi-site patient-centered PCT created opportunities for engagement of both patients/families and clinicians that led to high levels of enrollment.

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