Safer Use of Antipsychotics in Youth (SUAY)

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| **Project Name:**  Safer Use of Antipsychotics in Youth (SUAY) | |
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| **Principal Investigator institution:**  Kaiser Permanente Washington Health Research Institute |  |
| **Funder** NIMH |  |
| **Funding Period:**  Base period: 04/2016 – 12/2016 Option period 1: 12/25/16-12/24/17 Option period 2: 12/25/17-06/24/2021 |  |
| **Abstract:**  This pragmatic trial is testing an algorithm to improve prescribing of antipsychotics to youth with non-psychotic disorders. The project is inspired by the Partnership Access Line (PAL) and Second Opinion program operated for the Washington State Medicaid program. The project has 3 separately-funded phases: (1) planning and development, (2) feasibility pilot study at 2 sites, and (3) full scale pragmatic effectiveness trial at 4 sites. Under the SUAY protocol, a Second Opinion review by a child psychiatrist is triggered for new antipsychotics prescriptions when a set of pre-established criteria are met. We also offer 6 months of behavioral health navigation to support access and engagement with therapy in the health system and up to 9 clinic-to-home video-therapy sessions to bridge wait times to access in-person therapy. Outcomes will be assessed at 6 months. |  |
| **Contract Number:**  HHSN271201600002C |  |
| **Participating Sites:** Kaiser Permanente Washington (KPWA) Seattle Children’s Hospital (SCH) Kaiser Permanente Colorado (KPCO) Henry Ford Health System (HFHS) Nationwide Children’s Hospital (NCH) / Partners for Kids (PFK) University of Washington (UW) |  |
| **Investigators:** Robert Penfold, PhD – Kaiser Permanente Washington Health Research Institute Greg Simon, MD, MPH – Kaiser Permanente Washington Health Research Institute  James Ralston, MD, MPH – Kaiser Permanente Washington Health Research Institute  Clarissa Hsu, PhD – Kaiser Permanente Washington Health Research Institute  Rebecca Yates Coley, PhD – Kaiser Permanente Washington Health Research Institute  Tobias Dang, MD – Kaiser Permanente Washington Behavioral Health Services  Robert Hilt, MD – Seattle Children’s Hospital  Kathleen Myers, MD – Seattle Children’s Hospital  Kelly Kelleher, MD – Nationwide Children’s Hospital (NCH) /Partners for Kids (PFK)  Brian Ahmedani, PhD – Henry Ford Health System  Arne Beck, PhD – Kaiser Permanente Colorado  Andrea Hartzler, PhD – University of Washington (base period and option period 1) Paul Fishman, PhD – University of Washington |  |
| **Major Goals:** Base period (8 months): Develop a treatment algorithm and step-by-step clinical workflow that aims to promote the safer use of antipsychotics in youth aged 3-17 years who do not have a psychotic disorder, autism spectrum disorder, or intellectual disability.  Base period activities include convening a consensus panel of national experts to develop the treatment algorithm; interviewing youth, parents, and prescriber clinicians; conducting user-centered design sessions with prescribing clinicians and psychiatrists; and preparing for an option period 1 pilot study.  Option period 1 (12 months): Conduct a pilot study to test the feasibility, acceptability, reproducibility and implementation of the intervention and workflow in two health systems (20 patients per clinical site).  Group Health and Nationwide Children’s Hospital will participate in the pilot.  Option period 2 (3 years, 6 months): Conduct a full-scale pragmatic effectiveness study comparing usual care to enhanced usual care at four health system (200 patients enrolled per clinical site). Group Health, Nationwide Children’s Hospital, Henry Ford Health System, and Kaiser Permanente Colorado will participate in the pragmatic trial. |  |
| **Description of study sample:**  Provider subjects: The study will pre-randomize clinicians credentialed to prescribe medications in the health systems’ internal deliver system electronic medical record. Providers will be randomized to one of two arms: (1) usual care control and (2) intervention arms.  Patient subjects: Patients between the ages of 3 and 17 not already prescribed an outpatient antipsychotic and not suffering from a psychotic disorder, mania, autism spectrum disorder or intellectual disability.  Patient subjects will be added to a study log when a randomized provider enters an antipsychotic medication order for them in Epic. |  |
| **Current Status:**  The team achieved all option period 1 contract deliverables in December 2017. These include a final report summarizing findings and de-identified data from the pilot. and Option period 2 was awarded for the period 12/25/2017 through 6/24/2021. The DSMB approved the trial protocol and the NIH approved Human Subject activities to begin at KPWA, Nationwide, and KPCO in acknowledgement of IRB approval at those sites. IRB approval is pending at Henry Ford as of March 30, 2018. The study fielded at the first clinical site on March 29, 2018. The trial is set to field at KPCO on April 9, 2018; at Henry Ford in late-April and at Nationwide is May 2018. |  |
| **Study Registration:**  The trial is registered in ClinicalTrials.gov under record number NCT03448575. |  |
| **Publications:**  Three manuscripts are currently in development. |  |
| **Resources:**   * Clinical guidelines developed by a national panel of experts for the safer prescribing of antipsychotic prescribing in youth. * Epic build package. * Study protocol and manual of procedures. |  |
| **Lessons Learned from the Pilot:** Providers in the pilot study did not find the best practice alert to be burdensome. The review of prescribing decisions by a child and adolescent child psychiatrist was received less well by providers at Kaiser Permanente Washington than by those at Nationwide Children’s Hospital where the psychiatrist was internal and well known to the prescribing providers. Study materials were modified to provide feedback in a more structured and consistent way to prescribers, along with additional contextual messaging. The lack of a reliable and detailed knowledgebase on networked providers at KPWA was a barrier to providing effective and timely navigation during the pilot. Since that time, we have been working to build a more usable knowledgebase for both study and health system use. Numerous unknowns around the delivery of telemental health therapy to youth in WA state have been explored as well. This study stands in an unchartered space between research and usual care with respect to documentation requirements. We are paving the way for delivery of this kind of care at KPWA and learning much that will benefit the health system later, should they opt to take tele-therapy to scale. |  |
| **What’s next?** Recruitment will be ongoing for the large pragmatic effectiveness study over the next 2 years at the four clinical sites: Kaiser Permanente Washington, Nationwide Children’s Hospital, Kaiser Permanente Colorado, and Henry Ford Health System. Data and safety monitoring board reports will be prepared and delivered three times per year. |  |