

in a New York City hospital, and to determine the impact of the COVID-19 pandemic.

**Methods.** This IRB-approved study reviewed the medical records of 1101 child and adolescent patients that were psychiatrically hospitalized between June 1 2018 and November 30 2021 at Mount Sinai Morningside. Sociodemographic and clinical information was collected and analyzed using SPSS.

**Results.** In this sample, 29.4% of patients received psychotropic polypharmacy. The polypharmacy group contained a higher percentage of males, White patients, and fewer Asian/South Asian patients. They had on average more hospitalizations, a longer hospitalization period, and were more likely to be diagnosed with an impulsive/behavioral disorder, developmental disorder, or bipolar spectrum disorder. The polypharmacy group were twice as likely to receive medication for agitation while hospitalized. A regression model identified positive predictors of polypharmacy as having a history of violence and a higher number of psychiatric hospitalizations. Negative predictors included non-White race. White patients had the highest average number of medications and Asian/South Asian patients had the lowest. No impact of the COVID-19 pandemic was found.

**Conclusion.** Psychiatric polypharmacy is extremely common in the child and adolescent population that requires psychiatric hospitalization. Increased behavioral needs, such as episodes of violence, as well as greater illness severity, as indicated by greater number of hospitalizations, may be the driving factors behind polypharmacy. Further investigation is indicated to determine other contributing causal factors and to track long-term consequences of psychiatric polypharmacy.

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## Safety and Tolerability of KarXT (Xanomeline Trospium): Pooled Results From the Randomized, Double-Blind, Placebo-Controlled EMERGENT Trials

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**Introduction.** In prior studies, the dual M<sub>1</sub>/M<sub>4</sub> preferring muscarinic receptor agonist xanomeline demonstrated antipsychotic activity in people with schizophrenia and Alzheimer's disease, but its further clinical development was limited primarily by gastrointestinal side effects. KarXT combines xanomeline and the peripherally restricted muscarinic receptor antagonist trospium chloride. KarXT is designed to preserve xanomeline's beneficial central nervous system effects while mitigating adverse events (AEs) due to peripheral muscarinic receptor activation. The

efficacy and safety of KarXT in schizophrenia was demonstrated in the 5-week, randomized, double-blind, placebo-controlled EMERGENT-1 (NCT03697252), EMERGENT-2 (NCT04659161), and EMERGENT-3 (NCT04738123) trials.

**Methods.** The EMERGENT trials enrolled people with a recent worsening of positive symptoms warranting hospitalization, Positive and Negative Syndrome Scale total score  $\geq 80$ , and Clinical Global Impression–Severity score  $\geq 4$ . Eligible participants were randomized 1:1 to KarXT or placebo. KarXT dosing (xanomeline/trospium) started at 50 mg/20 mg twice daily (BID) and increased to a maximum of 125 mg/30 mg BID. Safety was assessed by monitoring for spontaneous AEs after administration of the first dose of trial drug until the time of discharge on day 35. Data from the EMERGENT trials were pooled, and all safety analyses were conducted in the safety population, defined as all participants who received  $\geq 1$  dose of trial drug.

**Results.** A total of 683 participants (KarXT, n=340; placebo, n=343) were included in the pooled safety analyses. Across the EMERGENT trials, 51.8% of people in the KarXT group compared with 29.4% in the placebo group reported  $\geq 1$  treatment-related AE. The most common treatment-related AEs occurring in  $\geq 5\%$  of participants receiving KarXT and at a rate at least twice that observed in the placebo group were nausea (17.1% vs 3.2%), constipation (15.0% vs 5.2%), dyspepsia (11.5% vs 2.3%), vomiting (10.9% vs 0.9%), and dry mouth (5.0% vs 1.5%). The most common treatment-related AEs in the KarXT group were all mild or moderate in severity.

**Conclusions.** In pooled analyses from the EMERGENT trials, KarXT was generally well tolerated in people with schizophrenia experiencing acute psychosis. These findings, together with the efficacy results showing a clinically meaningful reduction in the symptoms of schizophrenia, support the potential of KarXT to be the first in a new class of antipsychotic medications based on muscarinic receptor agonism and a well-tolerated alternative to currently available antipsychotics.

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## S.C.O.P.E. : Schizophrenia Clinical Outcome Scenarios and Patient-Provider Engagement Platform The Interactive Long-Acting Injectable Antipsychotics Selector

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**Introduction.** Healthcare professionals (HCPs) face unique challenges when managing patients with schizophrenia. Educational initiatives targeting common clinical dilemmas encountered by clinicians, such as unfamiliarity with prescribing information for long-acting injectable antipsychotics (LAIs), may assist clinicians when treating patients with schizophrenia.

**Methods.** Four experts in schizophrenia management used empirical evidence to identify 11 key clinical dilemmas where LAIs may be useful. These experts then developed a heuristic, educational tool (S.C.O.P.E.<sup>™</sup>: Schizophrenia Clinical Outcome Scenarios and Patient-Provider Engagement) based on empirical evidence and expert opinion for clinicians to use when encountering similar scenarios to optimize schizophrenia care. S.C.O.P.E.<sup>™</sup> also includes supportive elements such as an LAI selector.

**Results.** S.C.O.P.E.<sup>™</sup> is a freely available resource comprising an interactive digital platform providing educational materials for HCPs involved in continued care for patients with schizophrenia. To acquaint HCPs with characteristics of common LAIs used in schizophrenia treatment, S.C.O.P.E.<sup>™</sup> offers a selector that filters LAIs by approved indication(s), initiation regimen, reconstitution, dosing strengths and frequency, injection volumes and routes, and supply and storage information based on approved product labels. The LAI selector does not provide LAI safety and efficacy data, so HCPs should visit individual product websites for this information. Therefore, S.C.O.P.E.<sup>™</sup> will not replace clinical judgment, guidelines, or continuing medical education, and is not a platform for recording patient-level data, nor intended for payer negotiations or access-related questions by HCPs.

**Conclusions.** S.C.O.P.E.<sup>™</sup> is an educational tool for HCPs to use alongside standard psychiatric evaluations to improve understanding of how to manage common clinical dilemmas when treating patients with schizophrenia, the role of LAIs in schizophrenia management, and the product characteristics of available LAIs.

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## Introducing S.C.O.P.E. : Schizophrenia Clinical Outcome Scenarios and Patient-Provider Engagement An Interactive Digital Platform to Educate on Schizophrenia Care

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**Introduction.** Healthcare professionals (HCPs) face unique challenges when managing patients with schizophrenia. Educational initiatives targeting common clinical dilemmas encountered by clinicians, including partial or nonadherence, may alleviate knowledge gaps and clarify the role of long-acting injectable antipsychotic agents (LAIs) in treating this population.

**Methods.** 4 experts in schizophrenia management used empirical evidence to identify 11 key clinical dilemmas where LAIs may be useful. These experts then developed a heuristic, educational tool (S.C.O.P.E.<sup>™</sup>: Schizophrenia Clinical Outcome Scenarios and Patient-Provider Engagement) based on empirical evidence and expert opinion for clinicians to use when encountering similar scenarios to optimize schizophrenia care.

**Results.** S.C.O.P.E.<sup>™</sup> is a freely-available resource comprising an interactive digital platform providing educational materials for HCPs involved in continued care for patients with schizophrenia. S.C.O.P.E.<sup>™</sup> provides HCPs with considerations in common clinical scenarios met in inpatient and outpatient settings, as well as questions to consider when patients present to the emergency department. The potential usefulness of LAIs is explored in each scenario. Clinical education videos prepare nurse practitioners, social workers, and case managers to address patient concerns and communicate the benefits of LAI treatment. S.C.O.P.E.<sup>™</sup> will not replace clinical judgment, guidelines, or continuing medical education, and is not a platform for recording patient-level data, nor intended for payer negotiations or access-related questions by HCPs.