OBJECTIVE: To determine whether amphetamine extended-release oralsuspension (AMPH EROS) has an onset of effect at 30 minutes postdose inchildren with ADHD.

METHODS: This randomized, double-blind, 2-treatment, 2-sequence, placebo-controlled crossover pilot study enrolled subjects aged 6 to 12 years withattention-deficit/hyperactivity disorder (ADHD) and ADHD-Rating Scale-5 scores of ≥90th percentile for sex and age. A dose of 5 to 20 mg/day of AMPH EROS was determined during a 1-week open-label phase based on medication history, symptom control, and tolerability. Subjects completed a practice laboratory classroom then received one day of double-blind active drug or placebo each in random sequence during 2 double-blind laboratory classroom days. Subjects completed the first double-blind laboratory classroom session, returned to open label drug for 5 days then crossed over on day 6 during a second double-blind laboratory classroom session. DB dose was fixed at AMPH EROS 15, 17.5, or 20 mg . The primary endpoint was change from predose in the Swanson, Kotkin, Agler, M-Flynn, Pelham rating scale-combined score (SKAMP-C) at 30 minutes postdose on two DB days. The key secondary endpoint was change from predose in the SKAMP-C score at 3 hours postdose for AMPH EROS compared with placebo. Safety assessments included vital signs and adverse events.

RESULTS: Eighteen subjects were enrolled in the study (14 males and 4 females) with a mean age of 9 years. At both 30 minutes and 3 hours postdose, changes from baseline in SKAMP-C for AMPH EROS vs. placebo were statistically significant ($p < 0.01$ and $p = 0.0002$, respectively) with corresponding effect sizes of 0.96 and 1.57. Adverse events (>10%) during the open-label phase included upper respiratory tract infection, fatigue, upper abdominal pain, headache, decreased appetite, and affect lability.

CONCLUSIONS: AMPH EROS was effective in reducing ADHD symptoms at 30 minutes postdose. AEs were mild or moderate and consistent with those of other extended-release amphetamines.

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An Intervention to Decrease Benzodiazepine Prescribing by Providers in an Urban Clinic

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ABSTRACT: STUDY OBJECTIVES: Outpatient benzodiazepine use can cause side effects including dependence (20–30%) and death from respiratory depression when used with alcohol or opioids. Benzodiazepine use is on the rise in the U.S., increasing 67% from 1996–2013. In this quality improvement project, two educational interventions were combined with the intent of decreasing benzodiazepine prescribing by providers (MDs, APRNs) in an urban university clinic.

STUDY QUESTION: When prescribers working in a low-income clinic receive an intervention to increase awareness of benzodiazepine dangers and promote harm reduction strategies compared to treatment as usual, do they write fewer benzodiazepine prescriptions in the month following the intervention?

METHOD: A hybrid intervention combining academic detailing (educational outreach visits) and pharmaceutical industry detailing (merchandising, relationship building) was provided in two sessions to family practice providers (salaried and residents) working in a university outpatient clinic in Chicago. The subject matter included benzodiazepine risks, alternative treatments for anxiety & insomnia, and methods to deal with patient demand. All clinic providers ($n = 40$) were invited to participate. Participants were self-selected to attend each session (although resident physicians were obligated to attend). A total of 20–24 providers attended each session.
Benzodiazepine prescription information was extracted by clinic information systems for two periods: 12 months pre-intervention, and 30 days post-intervention. For ease of comparison, each prescription was converted to a common denominator: the diazepam-equivalent dose. The pre-intervention monthly average (for one year) was compared to 30-day post-intervention data. The outcome measure was the numeric difference in the prescribed diazepam-equivalents pre- and post-intervention. This number was used as a measure of the effectiveness of the intervention. A decrease in prescribing post- compared to pre-intervention would indicate a successful intervention.

RESULTS: There was an 80% decrease in benzodiazepine prescribing in the 30-day post-intervention period compared to the 12-month pre-intervention monthly average. This result cannot be explained by personnel changes at the clinic. Although these did occur in 2017, the pattern of prescribing was stable throughout the year prior to this intervention.

CONCLUSIONS: The combination of academic and pharmaceutical industry detailing influenced family practice

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providers in an urban clinic setting to decrease benzodiazepine prescribing by 80%. Decreased benzodiazepine prescribing should decrease patient morbidity and mortality.

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Long-Term Deutetrabenazine Treatment Response in Tardive Dyskinesia by Concomitant Dopamine-Receptor Antagonists and Baseline Comorbidities

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ABSTRACT: Background: Tardive dyskinesia (TD) results from exposure to dopamine-receptor antagonists (DRAs), such as typical and atypical antipsychotics. Clinicians commonly manage TD by reducing the dose of or stopping the causative agent; however, this may cause psychiatric relapse and worsen quality of life. In the 12-week ARM-TD and AIM-TD trials, deutetrabenazine demonstrated statistically significant improvements in Abnormal Involuntary Movement Scale (AIMS) scores versus placebo and was generally well tolerated, regardless of baseline DRA use or comorbidities.

STUDY OBJECTIVE: To evaluate the impact of underlying disease and current DRA use on efficacy and safety of long-term therapy of deutetrabenazine in patients with TD.

METHOD: Patients with TD who completed ARM-TD or AIM-TD were eligible to enter this open-label, single-arm, long-term extension after completing the 1-week washout period and final evaluation in the blinded portion of the trial. Change in AIMS scores from baseline to Week 54 and patients "Much Improved" or "Very Much Improved" (treatment success) on the Clinical Global Impression of Change (CGIC) and Patient Global Impression of Change (PGIC) at Week 54 were analyzed by baseline psychiatric illness type, including mood disorders (bipolar disorder/depression/other) or psychotic disorders (schizophrenia/schizoaffective disorder), and presence or absence of current DRA use.

RESULTS: At Week 54, meaningful improvements from baseline in mean (standard error) AIMS scores were observed for patients with baseline mood disorders (–5.2 [0.93]) and psychotic disorders (–5.0 [0.63]), and in patients currently using DRAs (–4.6 [0.54]) or not using DRAs (–6.4 [1.27]). Most patients with mood disorders (73%) and psychotic disorders (71%) were "Much Improved" or "Very Much Improved" on CGIC at Week 54, similar to patients currently using (71%) or not using (74%) DRAs. The majority of patients with mood disorders (62%) and psychotic disorders (57%), as well as patients currently using (58%) or not using (63%) DRAs, were also "Much Improved" or "Very Much Improved" on PGIC at Week 54. Prior treatment in ARM-TD and AIM-TD did not impact the long-term treatment response. Underlying psychiatric disorder and concomitant DRA use did not impact the occurrence of adverse events (AEs). The frequencies of dose reductions, dose suspensions, and withdrawals due to AEs were low, regardless of baseline psychiatric comorbidities and DRA use.

CONCLUSIONS: Long-term deutetrabenazine treatment demonstrated meaningful improvements in abnormal movements in TD patients, which were recognized by clinicians and patients, regardless of underlying psychiatric illness or DRA use.

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Long-term Improvements in Site-Rated Outcomes with Deutetrabenazine Treatment in Patients with Tardive Dyskinesia

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