Drug Use Evaluation: Use of Antipsychotics in Children

Research Questions:
1) How frequently are antipsychotics prescribed to antipsychotic-naïve children with FDA-approved or guideline endorsed indications?
2) What is the duration of therapy for newly started antipsychotics in children?
3) Which prescriber types and specialties are associated with new-start antipsychotics in children?

Conclusions:
1) Since 2009, gross and per member per month rates of newly started antipsychotics in children have been steadily declining. However, it is unclear from these data if the decline corresponds to changes in the target patient population, implemented initiatives, or provider preferences.
2) FDA-approved antipsychotic indications were infrequently found in children receiving their first antipsychotic (autism spectrum disorders (16%), bipolar disorder (4%) and schizophrenia (4%).
   a) Initiation of antipsychotic therapy in children is most commonly associated with Affective Disorders (excluding Bipolar disorder), Attention-Deficit/Hyperactivity Disorder (ADHD), Adjustment Disorder and Acute Stress Reactions.
   b) In children 0-5 years of age, initiation of antipsychotic therapy is most commonly associated with ADHD, Developmental Disorders and Disruptive Behavior Disorders.
3) The most common duration of therapy was categorized as short-term (43%).
   a) Duration of therapy did not appear to be associated with identified indications or prescriber specialties.
   b) There were 275 children under the age of 10 years who received either intermittent or long-term therapy.
4) Antipsychotics were initiated most commonly by mental health specialists (57%).
   a) 18% of new starts were prescribed by providers specializing in pediatrics.
   b) 7% of new starts were prescribed by providers specializing in family medicine.
   c) A minority of providers (5.5%) accounted for 34% of newly started antipsychotics.

Recommendations:
1) Develop a RetroDUR program which provides new start patients access to care coordination and referral for expert consultation. Profiles of patients who are less than 10 years of age and prescribed long-term therapy will be referred for expert review. Experts can then coordinate with prescribing providers in order to improve patient care.
Background
Since the 1990s, several studies have noted an increased trend in use of antipsychotic medications in children and adolescents.\textsuperscript{1-3} For example in the Texas Medicaid population, the number of prescriptions for children and adolescents increased 494\% between 1996 and 2000 for second generation antipsychotics.\textsuperscript{1} Similarly in the Tennessee Medicaid population, from 1996 to 2001 new users of atypical antipsychotics increased from 6.8\% to 95.9\%.\textsuperscript{4} Utilization which paralleled state Medicaid trends was also observed in a national study completed in 2006.\textsuperscript{5} Other studies noted that, in the absence of any comorbid psychiatric diagnosis, ADHD-diagnosed foster care children had more than 3-fold greater adjusted odds of atypical antipsychotic use than did children enrolled in income-eligible Medicaid categories.\textsuperscript{6} Nearly one-third of such ADHD-diagnosed foster care children received atypical antipsychotics regardless of age group, with annual duration of use more than 250 days in children ages 2 to 12 years.\textsuperscript{6}

These trends are particularly concerning due to the lack of good quality evidence addressing the safety and efficacy of antipsychotics in children. Initiation of antipsychotic therapy in children is most commonly associated with Affective Disorders (excluding Bipolar Disorder), Attention-Deficit/Hyperactivity Disorder (ADHD), Adjustment Disorder and Acute Stress Reactions. Adjustment Disorder is defined as an emotional or behavioral reaction to a stressful event or change in a child’s life.\textsuperscript{7} Acute Stress Reactions occur when a child has a very strong reaction to a life changing event such as death or illness in their family, a serious injury, or a natural disaster. An AHRQ systematic review of antipsychotics in children found mixed strength evidence for the use of antipsychotics in this population.\textsuperscript{8} In patients with ADHD and Disruptive Behavior Disorder, Bipolar Disorder, and Schizophrenia, there was moderate strength of evidence for the improvement of clinical global impression (CGI) scores with the use of second generation antipsychotics over placebo.\textsuperscript{8} Similar improvements in behavioral symptoms were noted for children with ADHD and Disruptive Behavior Disorder and for improvements in tics associated with Tourette Syndrome with antipsychotics compared to placebo.\textsuperscript{8} Outside of these outcomes, evidence was of low or insufficient quality for treatment of other conditions, for children under 6 years of age for any indication, and for combination treatment with multiple antipsychotics.\textsuperscript{8} Guidelines from the American Academy of Child and Adolescent Psychiatry (AACAP) for the use of psychotropic medication in children, calls for “a marked amount of caution” when considering treatment with antipsychotics.\textsuperscript{9} Due to the lack of long-term safety and efficacy data, guidelines recommend that long-term therapy should be reassessed based on patient needs and changing environments and not be assumed as the appropriate course of action. Similar recommendations were echoed by a U.S. Department of Health and Human Services report in 2015. The report raised concerns regarding the quality of care for Medicaid-enrolled children on psychotropic and antipsychotic medications.\textsuperscript{10} Sixty-seven percent of Medicaid claims reviewed revealed quality issues including: Medication Taken Too Long (34\%), Wrong Treatment (41\%), and Poor Monitoring (53\%).\textsuperscript{10}

Due to the rapid increase in use and the lack of high quality data supporting efficacy of these medication, particularly for Medicaid children within the foster care system, the Centers for Medicare and Medicaid Services (CMS) recommended State Medicaid programs monitor and oversee use of psychotropic medications for in children in foster care. In 2010, Oregon statutes were amended to insure children in foster care are appropriately assessed and any mental health disorders are diagnosed early.\textsuperscript{11} An assessment by a qualified mental health professional, except in emergency situations, is required prior to prescribing a psychotropic for a foster child under 6 years of age; any foster child receiving an antipsychotic; and any foster child prescribed 3 or more psychotropics. Psychotropic medications included under this policy are listed in Appendix 2. Annual medication reviews are also required for these foster children.\textsuperscript{12} Currently, the Drug Use Research and Management (DURM) program at the Oregon State University College of Pharmacy assists the Child Welfare program to identify and evaluate individual patient cases for children in the foster care system. Profiles for children who may benefit from additional care coordination are forwarded to advocates in the foster care system who then work with prescribers and psychiatric consultants at the Oregon Psychiatric Access Line about Kids (OPAL-K) to

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improve therapy for the children. OPAL-K is an organization at Oregon Health and Science University which provides physician to physician, patient-specific consultation service for primary care providers in Oregon.

Additional policies which have been adopted by the Oregon Drug Use Review / Pharmacy & Therapeutics (P&T) committee have included initiatives to promote annual metabolic monitoring for patient receiving antipsychotics and interventions to review the most complex regimens (5 or more concurrent psychotropics, 2 or more concurrent antipsychotics, and psychotropic use in children under 6 years of age). Since 2009, gross and per member per month rates of newly started antipsychotics in children have been steadily declining (Figures 1 and 2). However, it is unclear from these data if the decline corresponds to changes in the target patient population, implemented initiatives, or provider preferences. Since the start of these initiatives, there has been a 5% decrease (from 28% to 23%) in the prevalence of antipsychotics in children receiving at least one psychotropic.\textsuperscript{13-16} This decrease was likely because of Medicaid expansion in January 2014 and not due to the quality improvement initiatives. Similarly, in a recent review of the policy to improve metabolic monitoring, annual rate of metabolic monitoring had only improved by 4.2%.

This report will attempt to gather information concerning when antipsychotics are used in children, for how long, and from which provider types in order to inform policy recommendations.
Figure 1. New start antipsychotic rate in children in the Oregon Medicaid program 2002-2015

Key: PMPM = Per Member Per Month. Denominator = All eligible children in Oregon Medicaid under 18 years old. Numerator = All eligible children in Oregon Medicaid under 18 years old with a newly started antipsychotic

\[ y = -0.2181x + 58.404 \]
Figure 2. Prevalence of antipsychotic use in children in the Oregon Medicaid program 2002-2015

Key: PMPM = Per Member Per Month. Denominator = All eligible children in Oregon Medicaid under 18 years old. Numerator = All eligible children in Oregon Medicaid under 18 years old with any prescription for an antipsychotic
Methods:
An observational longitudinal cohort design was used to identify patients starting antipsychotic medications. The cohort was defined as Medicaid members less than 18 years of age with an index event from 1/1/2014-12/31/2014. The index event (IE) was defined as the first paid FFS pharmacy claim for any drug listed in Table A1 (see Appendix 1) without a paid pharmacy claim 120 days prior to the paid date.

Patients were excluded if they had Medicare Part D coverage (benefit packages BMM, BMD, MND or MED). Patients were excluded if they had less than 75% days of Oregon Medicaid eligibility from 90 days prior to the index date to 365 days after the index date to ensure the most complete data possible.

Duration of therapy was assessed using the proportion of days covered (PDC). The PDC is the number of days covered by at least one antipsychotic medication prescription, divided by the number of days in the evaluation period. PDC differs from medication possession ratio (MPR) in several ways, the most salient difference being MPR uses the first and last prescription date, whereas the PDC use the first prescription date and the end date of the evaluation period. MPR may overestimate adherence rates for patients who discontinue medications. Short-term therapy was defined as a PDC of 33% (i.e. 120-day supply) or less for the 365 days following the IE. Long-term therapy was defined as a PDC exceeding 80%. Intermittent therapy was defined as a PDC greater than 33% and less than 80%. Intermittent therapy represents either continuous prescribed therapy with low adherence or high adherence to moderate duration therapy.

Indications for the use of antipsychotics were determined using International Classification of Disease (ICD) codes from 12 months prior to the IE and 90 days after the IE. A list of all ICD codes and categorizations (e.g. Developmental Disorders, Adjustment and Acute Reactions, etc.) appears in Table A2. Baseline characteristics of age, gender, foster care status and ethnicity were assessed at the IE. Prescriber specialties were assessed using the National Provider Identifier (NPI) number associated with the IE and the associated taxonomy.
Results:
Baseline demographics appear in Table 1. The majority (74%) of antipsychotics initiated in children were in children 10 years of age and older.

Associated diagnosis data are summarized in Tables 2 and 3. Table 2 lists psychiatric diagnoses found in patients receiving newly started antipsychotics. The most commonly found psychiatric disorders were Affective Disorders (excluding Bipolar) (59%), ADHD (49%), and Adjustment and Acute Reactions (43%). Table 3 shows diagnosis history by age group. Antipsychotic initiation in the presence of ADHD (62%), Disruptive Behavioral Disorders (57%) or Developmental Disorders (54%) were the most common indications found in children 0-5 years of age. The presence of ADHD and Adjustment and Acute Reactions were common in all age groups and were the most common diagnoses for children 6-9 years of age. Affective Disorders (excluding Bipolar) were the most common diagnoses identified in children 10-17 years of age (68%). Schizophrenia and bipolar disorder were the least frequently identified disorders in all age groups.

Duration of therapy data are described in Tables 4 and 5. Table 4 indicates antipsychotics were most commonly used for short-term treatment (42%) with an average of 57 days covered in the 365 days following the IE. Table 5 illustrates that duration of therapy varied somewhat by indication with short-term therapy the most common (mean 42%, range 30-55%), followed by intermittent therapy (mean 32%, range 27-38%) and long-term therapy (mean 26%, range 14-41%). There were 275 children under the age of 10 years who received either intermittent or long-term therapy.

The most common specialties for prescribers of the first antipsychotic were Child and Adolescent Psychiatrists (26%), followed by Mental Health Nurse Practitioners (17%) and Pediatric Physicians (14%) (Table 6). The average number of prescribed first antipsychotic per prescriber was skewed due to several outlier providers. A de-identified list of prescribers initiating antipsychotics in 10 or more children during the evaluation period is listed in Table 7. The 24 prescribers (5.5%) listed account for 406 new antipsychotic starts (34%). Top prescribers initiated long-term therapy with the slightly greater frequency vs. non-top prescribers (29% vs. 25%). Top prescribers initiated intermitted therapy at a similar rate to non-top prescribers (31% vs. 32%). A greater proportion of children were 6-9 years old when antipsychotics were initiated by top prescribers vs. non-top prescribers (76% vs 70%).
### Table 1. Demographics

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<td><strong>Age</strong></td>
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<td>M</td>
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### Table 2. New start antipsychotics in children by diagnosis

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<td>ADHD</td>
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<td>Adjustment and Acute Reactions</td>
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<td>43%</td>
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<tr>
<td>Other Psychotic Disorders</td>
<td>490</td>
<td>41%</td>
</tr>
<tr>
<td>PTSD</td>
<td>310</td>
<td>26%</td>
</tr>
<tr>
<td>Disruptive Behavior Disorders</td>
<td>310</td>
<td>26%</td>
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<tr>
<td>Other Mental Health Diagnosis</td>
<td>291</td>
<td>24%</td>
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<tr>
<td>Developmental Disorders</td>
<td>230</td>
<td>19%</td>
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<tr>
<td>Autism Spectrum Disorders</td>
<td>193</td>
<td>16%</td>
</tr>
<tr>
<td>Sleep Disorders</td>
<td>108</td>
<td>9%</td>
</tr>
<tr>
<td>Personality Disorders</td>
<td>60</td>
<td>5%</td>
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<tr>
<td>Schizophrenia</td>
<td>42</td>
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<tr>
<td>No Diagnosis Found</td>
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<tr>
<td>Bipolar</td>
<td>33</td>
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<tr>
<td><strong>Grand Total</strong></td>
<td>1193</td>
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Table 3. Indications and age groups

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<tr>
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<tr>
<td></td>
<td>#</td>
<td>%</td>
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<td>%</td>
<td>#</td>
<td>%</td>
<td>#</td>
<td>%</td>
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<td>Affective Disorders, Excluding Bipolar</td>
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<td>88</td>
<td>35%</td>
<td>597</td>
<td>68%</td>
<td>698</td>
<td>59%</td>
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<td>62%</td>
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<td>68%</td>
<td>375</td>
<td>43%</td>
<td>584</td>
<td>49%</td>
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<td>Adjustment and Acute Reactions</td>
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<td>44%</td>
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<td>58%</td>
<td>337</td>
<td>38%</td>
<td>509</td>
<td>43%</td>
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<tr>
<td>Other Psychotic Disorders</td>
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<td>244</td>
<td>28%</td>
<td>310</td>
<td>26%</td>
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<td>31%</td>
<td>118</td>
<td>13%</td>
<td>230</td>
<td>19%</td>
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<tr>
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<td>22%</td>
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<td>193</td>
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<td>Sleep Disorders</td>
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<td>28</td>
<td>11%</td>
<td>63</td>
<td>7%</td>
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<td>9%</td>
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<td>5%</td>
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<td>5%</td>
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<td>0%</td>
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<td>4%</td>
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<tr>
<td>Bipolar</td>
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<td>1%</td>
<td>29</td>
<td>3%</td>
<td>33</td>
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Table 4. Duration of Antipsychotic Therapy

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<th>Coverage Type</th>
<th>#</th>
<th>%</th>
<th>Average Days Covered</th>
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<tr>
<td>Short Term</td>
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<td>57</td>
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<tr>
<td>Intermittent</td>
<td>381</td>
<td>32%</td>
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<td>Intermittent</td>
<td>Long Term</td>
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<td>--------------</td>
<td>-----------</td>
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<tr>
<td>Affective Disorders, Excluding Bipolar</td>
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<td>ADHD</td>
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<tr>
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<td><strong>501</strong></td>
<td><strong>381</strong></td>
<td><strong>311</strong></td>
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*Table 5. Duration of therapy by indication*
<table>
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<tr>
<th>Provider Specialty</th>
<th>Patients</th>
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<th>Patients Per Prescriber</th>
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<tr>
<td>PHYSICIAN-PSYCHIATRY&amp;NEUROLOGY-CHILD&amp;ADOLESCENT PSYCHIATRY</td>
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Table 7. List of prescribers (deidentified) initiating antipsychotic therapy in 10 or more children during the one year evaluation period

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**Limitations and discussion:**

There are several limitations to this drug use evaluation. As with any retrospective claims analysis, diagnosis information may not accurately reflect the true clinical diagnosis. A paid pharmacy claim may not correspond to a patient actually taking a medication. The use of medication samples and inpatient hospitalizations may also produce apparent gaps in therapy where none exists. Despite these limitations, some studies suggest administrative claims data to have a high positive predictive value (96%) for detecting the presence of bipolar disorder and schizophrenia. The use of PDC to determine the length of therapy has not been validated and may not accurately represent the duration of therapy.
In Oregon Medicaid, antipsychotics were most commonly prescribed short-term (<120 days) for Affective Disorders (excluding Bipolar disorder), ADHD, Adjustment Disorder and Acute Stress Reactions. However, there were a significant portion of patients under 10 years of age who received intermittent or long-term therapy (n=275). Because there is limited evidence for use of antipsychotics in children and long-term safety or efficacy of these agents is unclear, further initiatives are necessary to improve quality of care for Medicaid children prescribed antipsychotics. Individual review of patient profiles for children less than 10 year of age on long-term antipsychotics could help to identify areas of improvement in therapy and enhance care coordination for this vulnerable patient population. Currently, patient-specific consultations for Oregon Medicaid foster care children receiving an antipsychotic or children prescribed 3 or more psychotropics are conducted by child psychiatrists at OPAL-K for foster children. Expansion of this collaboration to also include consultation and/or patient profile reviews for children on long-term antipsychotics could help to improve care coordination and provide resources for primary care physicians. Profiles of patients meeting criteria will be forwarded to child psychiatrists who can then consult with prescribing providers in order to improve care and optimize therapy if necessary.

References:


# Appendix 1: Reference Tables

## Table A1: Antipsychotics

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**This chart was compiled by DHS personnel and includes “off label” recommendations**

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<td><em>Expected benefits include: increased ability to focus, decreased distractibility, decreased impulsivity, decreased hyperactivity</em></td>
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<td>Methylphenidate (Ritalin, Methyl, Metadate)</td>
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<td>Amphetamine - Dextroamphetamine (Adderall)</td>
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<td>Dextroamphetamine (Dexedrine)</td>
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<td>Lisdexamfetamine (Vyvanse)</td>
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<td><em>Used to treat depression, phobias, panic attacks, anxiety, eating disorders, obsessive-compulsive disorders, PTSD, and ADHD</em></td>
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<td>Fluoxetine (Prozac)</td>
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**Category IV: Mood Stabilizers**

*Used to treat bi-polar disorder, excessive mood swings, aggressive behavior, impulse control disorder, and schizophrenia*

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**Category V: Anti-Psychotics**

*Used to treat schizophrenia, delusion, hallucinations, disorganized thinking, explosive aggression in conduct disorder, disruptive behavior, agitation in children with developmental delays (mental retardation, autism, etc.), tic disorders, Tourette’s Syndrome, adolescent bi-polar disorders, early onset psychotic depression, disruptive behaviors, and agitation in children with traumatic brain injuries*

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