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Antipsychotic Medication Prescribing Trends in Children and Adolescents

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Abstract

The Food and Drug Administration has approved the use of antipsychotic medications in some children and adolescents with severe emotional and behavioral disorders. However, recent national data show a dramatic rise in off-label and Food and Drug Administration–approved uses of these medications. Of particular note is a twofold to fivefold increase in the use of antipsychotic medications in preschool children, despite little information on their long-term effects. This article describes the trend in pediatric antipsychotic medication use, possible explanations for the increase, implications for children's health, and recommendations for pediatric providers who work with parents of children and adolescents who seek or receive antipsychotic medication treatments.

Keywords

Child mental illness; antipsychotics in children; prescribing trends

Approximately 14% to 20% of children and adolescents have a diagnosable mental illness, with an annual cost that is estimated to be $247 billion (National Research Council and Institute of Medicine, 2009). Children with emotional and behavioral disorders are more likely to be expelled from preschool, require special education and health care services, become involved in the juvenile justice system, and become chronically ill and unemployed as adults (Currie & Stabile, 2006; National Research Council and Institute of Medicine, 2009). As a result, parents, providers, payers, and policy makers are eager to find effective but relatively inexpensive mental health treatments that can quickly stop children's disruptive behaviors before they become chronic, disabling, and intractable. Particularly challenging for parents and teachers are severe conduct problems such as aggression and impulsivity that can be harmful and destructive to others. It is not uncommon for parents of these children to feel overwhelmed and frightened for their own and their other children's

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well-being (Bussing et al., 2003; Larson, Russ, Kahn, & Halfon, 2011; Muris, Meesters, Morren, & Moorman, 2004). Under these circumstances, psychotropic medications, including antipsychotic agents, may be recommended as part of a comprehensive treatment plan for managing children's behavioral symptoms.

Although the Food and Drug Administration (FDA) has approved some antipsychotic medication treatment for children and adolescents with severe behavioral and emotional disorders, the most current national reports of prescribing trends reveal increases in both evidence-based use (i.e., FDA-approved use based on rigorously controlled trials demonstrating safety and efficacy) and off-label use (i.e., non-FDA approved applications based on insufficient evidence of safety and efficacy). Indeed, research shows that most children receiving antipsychotic medications are receiving them for non-approved psychiatric conditions (Pathak, West, Martin, Helm, & Henderson, 2010; Zito, Derivan, et al., 2008;). The purpose of this article is to describe the rising trend in pediatric antipsychotic medication use, possible reasons for the increase, implications for children's health, and recommendations for pediatric primary care providers who care for children with emotional and behavioral disorders.

ANTIPSYCHOTIC MEDICATIONS AND THEIR ADVERSE EFFECTS

The FDA has approved the use of select antipsychotic medications for children and adolescents for treatment of severe conduct problems that are resistant to other forms of treatment. Specific child psychiatric disorders include Tourette's syndrome and behavioral symptoms associated with autistic disorder, childhood schizophrenia, and bipolar disorder (Crystal, Olfson, Huang, Pincus, & Gerhard, 2009; Pathak et al., 2010). Medications approved for pediatric treatment of these disorders include haloperidol (Haldol), thioridazine (Mellaril), risperidone (Risperdal), aripiprazole (Abilify), quetiapine (Seroquel), olanzapine (Zyprexa), and ziprasidone (Geodon).

Haloperidol has been used to treat Tourette's syndrome, treatment-resistant severe behavior disorders, and treatment-resistant attention deficit hyperactivity disorder with conduct disorder (Findling, McNamara, &Gracious, 2003; Zito, Derivan, et al., 2008). Thioridazine has been prescribed for treatment-resistant severe behavior disorders, treatment-resistant attention deficit hyperactivity disorder with conduct disorder, and schizophrenia (see Zito, Derivan, et al. [2008] for a list of antipsychotic medications, age limits, and FDA-labeled uses in children, and see the Web site at http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/DrugSafetyInformation/default.htm for the most recent updates on approved uses). Haloperidol and thioridazine are classified as "first-generation" antipsychotic medications; they originally were developed for adults in the 1950s and were used to treat psychotic symptoms. However, these first-generation antipsychotic agents also can cause a number of severe and debilitating extrapyramidal adverse effects, including tardive dyskinesia (Sadock & Sadock, 2003).

Risperidone, aripiprazole, quetiapine, olanzapine, and ziprasi-done are classified as second-generation anti-psychotic medications or "atypical antipsychotics." They were first introduced in the 1990s and approved for limited pediatric use. These atypical antipsy-chotic medications work similarly to the first-generation anti-psychotic agents by blocking dopamine pathways but with less risk of causing extrapyramidal adverse effects. Moreover, research has supported their efficacy. For example, risperidone, the most commonly used antipsychotic medication for children, has been found to effectively reduce irritability, aggression, self-injury, tantrums, agitation, and mood swings in children with autism (Findling, Aman, Eerdekens, Derivan, & Lyons, 2004; McCracken, McGough, Shah, Cronin, & Hong, 2002).

However, these second-generation antipsychotic medications also have significant adverse effects. A review of clinical trials using atypical antipsychotic agents with children and adolescents revealed that these medications can cause weight gain and drowsiness and increase the risk of developing hyperglycemia, hyperlipidemia, hyperprolactinemia, and diabetes (De Hert, Dobbelaere, Sheridan, Cohen, & Correll, 2011). Cases of drooling also have been reported (McCracken et al., 2002). One study comparing the effects of risperdone to olanzapine found that preschool children gained an average of 6 lb over 6 weeks (Biederman et al., 2005).

Although adults receiving second-generation anti-psychotic medications are also at risk for these adverse reactions, children are physically and emotionally more vulnerable to the adverse effects because of their smaller size, developing physiology, and negative impact on peer perceptions (McCracken et al., 2002; Safer, 2004). Low-income children, who are already at greater risk for mental health problems and obesity, may be particularly vulnerable to these metabolic and endocrine abnormalities (Zito et al., 2007). In 2003, the FDA required all second-generation antipsychotic agents to include warning labels regarding the increased risks of diabetes mellitus, hyperglycemia, and severe hyperglycemia associated with ketoacidosis, hyperosmolar coma, or death (Morrato et al., 2010). The American Diabetes Association, American Psychiatric Association, North American Association for the Study of Obesity, and the American Association of Clinical Endocrinologists subsequently issued a joint consensus that expanded the FDA screening recommendations to include a monitoring protocol (Morrato et al., 2010). Please refer to the Table and the American Academy of Child and Adolescent Psychiatry (AACAP) Practice Parameter for the Use of Atypical Antipsychotic Medications in Children and Adolescents (AACAP, 2011) for a more detailed list of health parameters recommended for assessment and monitoring of children receiving or being considered for antipsychotic medication.

Despite the adverse effects, the FDA has approved risperidone for treatment of irritability and aggression in autistic children ages 5 to16 years and risperidone and aripiprazole for treatment of schizophrenia in children ages 13 to 17 years. More recently, four other atypical antipsychotic medications were approved for the treatment of bipolar 1 disorder and schizophrenia: quetiapine (Seroquel), olanzapine (Zyprexa), ziprasidone (Geodon), and aripiprazole (Abilify; for bipolar disorder only).

It is important to note that although the FDA has approved second-generation antipsychotic medications for these conditions, most pediatric use is off label, that is, prescribed for conditions not approved by the FDA (Crystal et al., 2009; Zito, Derivan, et al., 2008). In addition, a twofold to fivefold increase in the use of antipsychotic medications in children younger than 6 years has occurred, despite little information on their long-term effects on child health and the developing brain (Egger, 2010; Zito et al., 2000; Zito et al., 2007). Moreover, young children are likely to be receiving multiple psychotropic medications. In one large-scale analysis, almost 80% of preschool children receiving antipsychotic medications also were prescribed other psychotropic medications to manage their symptoms (Olfson, Crystal, Huang, & Gerhard, 2010). These trends, which are affecting both privately and publicly insured children of both sexes (Olfson et al., 2010; Pathak et al., 2010), pose significant implications for pediatric providers.

POSSIBLE REASONS FOR THE RISING TREND IN ANTIPSYCHOTIC USE

Many hypotheses have been generated to explain the increased use of antipsychotic medications in children and adolescents. Some of these explanations are described below.

Greater Acceptability of Psychotropic Medication Use in Children

During the past 15 years, an overall increase in pediatric use of psychotropic medications has occurred (Zito et al., 2000), which may create an environment of acceptability for prescribing antipsychotic medications. This environment of acceptability may be unique to the United States. A multinational comparison of administrative claims data for psychotropic medication use showed that the prevalence of antidepressant, stimulant, and antipsychotic medication use was 1.5 to more than 3 times greater in the United States than in Western European countries (Zito, Safer, de Jong-van den Berg, et al., 2008). Thus American families, who are already exposed to high levels of direct advertising from pharmaceutical companies, may be more open to treating mental health problems with medications.

Increased Knowledge and Awareness

Numerous studies published in peer-reviewed journals report convincing evidence that antipsychotic medications have been effective for reducing aggression and irritability in children and adolescents with psychiatric disorders (Biederman et al., 2005; Delbello et al., 2009; Delbello, Schwiers, Rosenberg, & Strakowski, 2002; Findling et al., 2004; Findling et al., 2009; Haas et al., 2009; Tohen et al., 2007). Most of these clinical trials have been published in the past 10 to 15 years, mirroring the time frame over which the rise in antipsychotic use has been observed. Also during this period, an increase in the diagnosis of childhood autism has occurred (Manning et al., 2011), a disorder that is often accompanied by aggression and for which risperdone has been shown to be effective (Arnold et al., 2010). Thus greater use may be due to both the expanding need and available clinical evidence that have occurred in the past decade.

Limited Access to Non-Pharmacologic Treatments

According to the most recent National Survey of Children's Health (Centers for Disease Control and Prevention, 2007), 40% of children ages 2 to 17 years did not receive mental health care or counseling during the preceding 12 months when they needed these services. At least in part, this treatment gap is due to the insufficient supply and uneven distribution of trained mental health professionals in the United States (Thomas & Holzer, 2006). A decline in access to and duration of inpatient treatment for children also has occurred (Case, Olfson, Marcus, & Siegel, 2007). As a result, relatively few children and adolescents are receiving psychiatric assessments or gaining access to non-pharmacologic treatments from trained mental health practitioners.

Demand for Quick and Affordable Treatments

Many evidence-based, behavioral, non-pharmacological treatments are now available for children with emotional and behavioral disorders (National Research Council and Institute of Medicine, 2009). However, these treatments often require 12 sessions or more to attain full benefit, and many families may not have sufficient insurance coverage to complete these therapies. Parent training and cognitive-behavioral therapies can be costly for families without adequate insurance and may seem too time-consuming for families in desperate need of a "quick fix." Under these circumstances, medication may be seen as an effective, affordable alternative.

Inadequate Provider Time and Reimbursement for Managing Behavioral Problems

Most mental health screening is conducted in pediatric primary care (United States Department of Health & Human Services, 2000). However, pediatric providers have limited time to conduct thorough behavioral assessments or to work with families struggling with their children's emotional and behavioral problems. Indeed, pediatric visits for behavioral

issues consume more of providers' time but are reimbursed at significantly lower rates than general medical visits (Meadows, Valleley, Haack, Thorson, & Evans, 2011). Lack of reimbursement for the time needed to fully assess children's problematic behaviors may put clinicians in a bind, particularly if they are faced with an overwhelmed parent desperate for help. Providers may also be concerned for the safety of the child and his or her family. Under these circumstances, medication may be seen as a viable course of treatment.

Limited Treatment Options for Vulnerable Populations

Many children and adolescents in the foster care system and in juvenile correctional facilities have psychiatric illness (Burns et al., 2004; McMillen et al., 2005). In a study comparing Medicaid-insured youth in and outside of foster care, Zito, Safer, Sai, and colleagues (2008) found that youth in foster care received psychotropic medications at more than three times the rate of Medicaid-insured children who were not in the foster care system; they also found that more than 53% of the psychotropic medications prescribed to low-income children in foster care were antipsychotic agents. Use of antipsychotic medications also is prevalent in juvenile corrections facilities, which house many violent teens with psychiatric illness (Moore, 2009). Foster care and juvenile corrections facilities are two contexts in which mental health care is severely under-funded and where the adults managing the children require access to treatments that can quickly bring aggressive behavior under control.

IMPLICATIONS FOR PEDIATRIC HEALTH CARE PROVIDERS

Increasing consensus exists that antipsychotic medication should be the treatment of last resort, after parenting skills training and other behavioral treatments have been tried and have failed (Gleason et al., 2007). Many of the causes of children's aggressive or disruptive behaviors are linked to family relationships and stressful, unpredictable home environments, which also may be violent and aggressive (National Research Council and the Institute of Medicine, 2009). Under these situations, antipsychotic medication is not an appropriate course of treatment because it does not address the underlying cause of the problem.

Prescribing antipsychotic medications may not be in the scope of practice for pediatric nurse practitioners or family nurse practitioners in some states, and each nurse practitioner should review the Scope of Practice for their state before considering prescribing antipsychotic medications to children or adolescents. However, should these medications be considered by primary care providers, collaboration with a psychiatrist or an advanced practice psychiatric/mental health nurse is essential for ensuring high-quality care (American Academy of Pediatrics and AACAP, 2009; International Society of Psychiatric Mental Health Nurses, 2010). Unfortunately, such collaborations are rare. In a recent study of young, privately insured youth, most children who were prescribed antipsychotic medications by a primary care provider had not received a mental health assessment, a psychiatrist visit, or any psychotherapy during the year in which the medications were prescribed (Olfson et al., 2010). Concern over the rising use of antipsychotic medications in children has led to a number of state-level initiatives to more closely monitor prescribing practices and build local collaborative arrangements between child psychiatry specialists and pediatric primary care providers to ensure that their use is safe and appropriate (Medicaid Medical Directors Learning Network & Rutgers Center for Education and Research on Mental Health Therapeutics, 2010).

Comprehensive psychiatric assessment prior to initiating psychotropic medication is important to determine the nature of the child's illness and whether antipsychotic medication is an appropriate course of action, as well as to provide oversight and consultation regarding use and dosing of these medications. For access to qualified psychiatric consultation

services, pediatric providers or parents usually can obtain referral information through their local health department or the family's health insurance provider. In many under-served areas, delivery of psychiatric consultations via telecommunications technology (i.e., long-distance consultation using audio or video technology) has also been shown to be effective (Shore et al., 2008; Spaulding, Belz, DeLurgio, & Williams, 2010). Ideally, children and their families also should be assisted with gaining access to evidence-based treatments, such as parenting skills training or cognitive behavioral therapy, before receiving medications or in conjunction with medications.

Because children with psychiatric illness represent a highly vulnerable population and much of the antipsychotic medication use in children is off label, obtaining informed consent from parents or legal guardians before medication is prescribed is important. Information should be provided, verbally or in writing, on (a) risks and benefits of antipsychotic medications, (b) the need for ongoing monitoring, (c) the potential harm if an abrupt cessation of these medications occurs (e.g., withdrawal dyskinesia), (d) other potential adverse drug events, and (e) whom to contact should adverse drug events occur (see "A Bill of Rights for Children with Mental Health Disorders and their Families" at www.aacap.org for more information). Finally, parents should demonstrate a full understanding of these issues before consenting to treatment with antipsychotic medications.

Before initiating antipsychotic medications, pediatric providers need to obtain baseline measures of the child's body mass index, liver function, blood pressure, and lipids and then monitor these indicators regularly. Although no standards exist for how frequent contact should be, it is appropriate for children to have weekly visits until they are stable on antipsychotic medications, and then monthly thereafter. During these visits, providers should talk with the parent or caregiver and the child to understand their perceptions of the treatment, the extent to which it is helping manage behavioral symptoms, and their satisfaction with the medication.

CONCLUSIONS

Although an increase in the off-label use of antipsychotic medications in children and adolescents has occurred, no standardized oversight exists to guide such use. Close monitoring in collaboration with a qualified mental health provider is needed to ensure safe prescribing practices. Given the significant adverse effects of antipsychotic medications and our limited knowledge of their long-term effects on children's health, open communication with parents or legal guardians about the potential risks, benefits, adverse effects, and need for frequent follow-up assessments is essential.

For more information, see the American Academy of Children and Adolescent Psychiatry Facts for Families at http://www.aacap.org/cs/root/facts_for_families/facts_for_families. The Bill of Rights for Children with Mental Disorders and their Families is available at http://www.aacap.org/galleries/transparency-portal/bill%20of%20rights%20FINAL.pdf.

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OBJECTIVES

1. Describe three reasons for the rising trend in the prescription of antipsychotic medications for children and adolescents with behavioral disorders.
2. List common adverse effects of Food and Drug Administration–approved medications for behavioral disorders.
3. Discuss recommendations for pediatric primary care providers in prescribing antipsychotic medications for children with emotional and behavioral disorders.

TABLE

Recommended baseline assessments for children receiving antipsychotic medications

Child's medical history and review of symptoms	Family history	Physical assessments (at baseline and regular intervals throughout treatment)	Measurement of movement disorders	ECG	Other drug-specific monitoring
Diabetes	Maternal or paternal history:	Body weight	Administer the Abnormal Involuntary Movement Scale	Required if there is a family history of sudden or unexplained deaths or cardiac abnormalities, or if the child has a history of syncope, palpitations, or cardiovascular abnormalities	EEG (clozapine) Ophthalmologic examination (quetiapine) ECG (ziprasidone)
Obesity	Diabetes	Body mass index			
Cardiovascular disease	Obesity	Waist circumference			
Seizures	Cardiovascular disease	Blood pressure			
Hypercholesterolemia	Seizures	Fasting plasma glucose			
Hyperlipidemia	Hypercholesterolemia	Fasting lipid profile:			
Cardiac abnormalities	Hyperlipidemia	Total cholesterol			
Other medications the child is receiving	General family history:	High-density lipoprotein			
	Sudden or unexplained deaths	Low-density lipoprotein			
	Cardiac abnormalities	Triglycerides			
	No. of siblings				
	Health status of siblings				

ECG, Electrocardiogram; EEG, electroencephalogram.

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