



The Center for
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Care in Schools

The School of Public
Health & Health Services

THE GEORGE WASHINGTON UNIVERSITY

Psychotropic Drugs and Children

A 2007 Update

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Background

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- #### Emotional and Behavioral Health Problems in Children
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Background

The safe and effective use of medications for the treatment of certain medical conditions and illnesses has enabled many children to attend school and achieve academic success.¹ In medical practice, widespread acceptance of drug therapy for behavioral disorders has facilitated diagnosis and treatment of these conditions in ambulatory care.²

Recent changes in the use of psychotropic medications by children and adolescents, and concerns about adverse consequences, have prompted the US Food and Drug Administration (FDA) to revise their guidance for prescribers and patients. The need for up-to-date drug information, and for monitoring of students on medication, prompted the Center to update this fact sheet for those who may be called upon to administer medications to students during the school day.

Emotional and Behavioral Health Problems in Children

- Studies show that at least one child in 5 has a mental, emotional, or behavioral disorder severe enough to cause some level of impairment. At least one child in ten has a mental illness severe enough to cause extreme functional impairment.^{3,4,5}
- A national survey of pediatricians showed that 19% of pediatric visits involved a psychosocial problem requiring attention or intervention. Psychosocial problems are the most common chronic condition for pediatric visits, eclipsing asthma and heart disease.²
- In 2006, 4.7 million children (8%) were reported to have a learning disability; 10% of boys were identified as having a learning disability, compared with 6% of girls.⁶
- Four and a half million children 3–17 years of age (7%) were reported to have Attention Deficit Hyperactivity Disorder (ADHD). Boys are more than twice as likely as girls to have ADHD (11% and 4%).⁶
- Research indicates that depression is present in 1% of children and 5% of adolescents at any given time. Before puberty boys and girls are at equal risk for depression; after puberty onset the rate of depression is twice as high for girls.⁷
- Up to half of all children with ADHD—mostly boys—also have oppositional defiant disorder (ODD), which is characterized by defiance and outbursts of temper. About 20% to 40% of ADHD children may eventually develop conduct disorder (CD), a more serious disorder characterized by behaviors such as lying, fighting, and other antisocial acts. These children tend to get into trouble in school, at home, and in their communities. Some children with ADHD (mostly younger children and boys) can also experience anxiety and depression.⁸
- Some evidence suggests an increasing prevalence of bipolar disorder in youth.⁹ Researchers find that children and adolescents show more intense but somewhat different symptoms than adults,¹⁰ but others note that it is difficult to apply standard diagnostic criteria to them.^{11,12} Until studies identify specific treatments for pediatric bipolar disorder, adult medications are prescribed off-label. Caution and close observation are warranted as some treatments for depression or co-occurring conditions—such as ADHD—can cause mania to develop in susceptible patients.⁹
- In 2006, there were 9.6 million children in the US (13%) who had a health problem for which medication had been taken regularly for at least 3 months. Boys (15%) were more likely than girls (12%) to have been on regular medication for at least 3 months. Overall, 16% of youths aged 12–17 years were on regular medication compared with 14% of children aged 5–11 years, and 8% of children under 5 years of age.⁶

Definition: Psychotropic drugs are those that affect the function, behavior, or experience of the mind.¹³ While their exact mechanism of action is not known, psychotropic drugs are thought to act upon the biochemistry of the brain and positively affect thinking mechanisms, emotional control, mood, and other behavioral processes. Included are neuroleptics (such as Haldol), antipsychotics (such as Zyprexa), antidepressants (such as Prozac), stimulants (such as Ritalin), and anti-anxiety agents (such as BuSpar).¹³

Psychotropic Drugs and Children

Treatment: What we know

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Treatment: What we know

- Stimulant and non-stimulant medications can be effective for the short-term treatment of ADHD.¹⁴ Some studies demonstrated that stimulants or stimulants in combination with behavioral treatments produce long-term improvements when the drug continues to be taken.¹⁵
- The use of selective serotonin reuptake inhibitor (SSRI) antidepressants to treat major depression in children and adolescents has been controversial. Many studies have shown SSRI agents to be only modestly effective in the treatment of major depression among adolescents.¹⁶ However, a large 2004 study by the National Institute of Mental Health (NIMH) concluded that the combination of fluoxetine [Prozac], approved for treatment of pediatric depression, with cognitive behavioral therapy (a form of talk therapy) was successful in helping 71% of the study's teenagers overcome depression. The Treatment for Adolescents with Depression Study (TADS) also showed that fluoxetine alone was effective in 61% of subjects, while talk therapy alone worked with 43%. Thirty-five percent of those who received a placebo also improved. Patients became significantly less suicidal, no matter which treatment they were given.¹⁷
- Children and adolescents with major depressive disorder who are treated with antidepressants, may experience suicidal thinking and behavior.¹⁸ The FDA's warning did not prohibit use of the medications in youth but called on physicians and parents to closely monitor children and adolescents taking antidepressants for any worsening in symptoms of depression or unusual changes in behavior.¹⁹
- The long-term effects of antidepressants on a child's developing nervous system have not been studied. Some physicians have expressed concern about the possibility of central nervous system problems after long duration therapy, or the development of additional disorders.²⁰ Questions also have been raised about the longer-term use of antidepressants, whether they would continue to be effective, and if effective, would produce more or different side effects.²¹
- The effectiveness of selective serotonin reuptake inhibitors (SSRIs) and clomipramine [Anafranil] for obsessive-compulsive disorder (OCD) has been indicated by a number of studies. The FDA approved the use of two SSRIs, fluvoxamine [Luvox] and sertraline [Zoloft], for use in pediatric OCD. Fluoxetine [Prozac] also is approved for use in pediatric OCD.²²
- An NIMH-funded study to test the efficacy and safety of medications commonly used to treat children and adolescents (in off-label applications), found that fluvoxamine, an SSRI antidepressant approved for treating OCD in children, was both safe and effective in treating social phobia, separation anxiety disorder, and generalized anxiety disorder in children 6–17 years of age.²³
- In 2007, the FDA approved use of risperidone [Risperdal] for the treatment of schizophrenia in adolescents ages 13–17, and for the short-term treatment of manic or mixed episodes of bipolar 1 disorder in children and adolescents, ages 10–17.²⁴ Risperdal was approved in 2006 for treatment of irritability associated with autistic disorder in children ages 5–16.²⁵
- Data reported by a pharmacy benefits manager indicated that use of antidepressants slowed considerably during 2005, in response to concerns about the risk of suicidality—especially during the first few months of therapy or when dosages are adjusted—but began to increase again in 2006. Approximately 7.8% of US schoolchildren (ages 4 to 17) have been diagnosed with ADHD, and about 4.3% of children currently receive medication for the condition.²⁵
- Between 2000 and 2005, ADHD treatment rates increased an average of 9.5% per year for children.²⁵
- Schools are often where students' mental health needs are discovered and where support is provided.²⁶ Fear and isolation can be harmful for students in treatment—but inclusion and caring can really help. Children and adolescents recover sooner and better when the environment is made a safer place for recovery.²⁷

FDA Advisories on Antidepressants, ADHD Medications

In May 2007, the FDA updated health advisories^{28,29} alerting prescribers to the increased risk of suicidal thinking and behavior that may occur in children, adolescents, and young adults 18–24 when antidepressant medication is started. Patients should be observed closely for signs of worsening illness, suicidality, or unusual changes in behavior. FDA also cautioned that depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide.²⁹ Patients will receive an updated MedGuide³⁰ with their prescription or renewal, informing them of the risks.

FDA cautioned in February 2007, that patients taking medications for ADHD should become aware of risks for possible development of cardiovascular complications, and/or adverse psychiatric symptoms.³¹ This information has been added to the MedGuides for ADHD medications.

In addition, patients taking SSRI or SNRI antidepressants should be cautioned that starting concurrent triptan medication for migraine can result in serotonin syndrome, a life-threatening condition characterized by fast heartbeat, hallucinations, restlessness, loss of coordination, nausea, vomiting, and diarrhea. Because these medications may be prescribed by different physicians, patients are cautioned to tell their health care provider what medications they are taking.³²

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Psychotropic Drugs Encountered in the Health Suite

* Symptoms associated with diagnosis.

** Observed effects of medication (side effects), improper dosing, medication conflicts, missed doses, discontinued medication, or individual adverse reactions.

Drug	Symptoms *	What To Watch For **
Drugs used for ADD and ADHD, including stimulants and non-stimulants		
STIMULANTS		
Ritalin, Metadate, Methylin, Concerta, Daytrana, Focalin, (methylphenidate/ dexmethylphenidate in various forms)	Signs of inattention include being easily distracted, failing to pay attention to details, making careless mistakes, not following directions, forgetting or losing things, failing to finish tasks, and skipping from one uncompleted task to another. ^{8,33} Signs of hyperactivity-impulsivity include fidgeting or squirming, running, climbing, or leaving a seat at inappropriate times, blurting out answers, and difficulty waiting in line or taking turns. ^{8,33} Combined type includes signs of both inattention and hyperactivity-impulsivity. ^{8,33}	Nervousness, insomnia, decreased appetite, weight loss, headaches, stomach aches, skin rash, jitteriness, and social withdrawal. ^{33,34} The FDA warns of serious cardiac and cardiovascular risks—including sudden death—associated with use of methylphenidate or dexmethylphenidate in children adolescents, and adults. ^{31,34} Overdose is characterized by vomiting, agitation, tremors, muscle twitching, convulsions, euphoria, hallucinations, delirium, sweating, and cardiac arrhythmias. Contact a poison control center. ³³
NON-STIMULANT		
Strattera (atomoxetine)	Symptoms of ADD and ADHD, above	Anxiety, agitation, panic attacks, insomnia, hostility, irritability, aggressiveness, mania. ³⁵
Antidepressants for depression, mood disorders, obsessive-compulsive disorder		
Prozac (fluoxetine) This is the only SSRI currently FDA approved for use with depression in pediatric populations. Prozac also is approved for pediatric OCD. ³⁶	Depression Persistent sad, anxious, or “empty” mood; feelings of hopelessness, pessimism; feelings of guilt, worthlessness and helplessness; loss of interest or pleasure in usual activities; slowed thinking or impaired concentration; a suicide attempt or suicidal thinking. ^{41,42}	Worsening depression, anxiety, agitation, panic attacks, insomnia, irritability; mania, impulsivity, restlessness; decreased appetite; rash or hives; thoughts of suicide, attempted suicide; in rare cases, seizure. ^{28,29,30,36,37,39,41} Suicidality: Patients should be closely monitored for signs of worsening illness, suicidal thoughts or actions, or unusual changes in behavior. ^{28,29,30,43} Serotonin Syndrome: Patients taking SSRI or SNRI antidepressants should be cautioned to tell their health care providers they are taking these medications prior to starting treatment with triptans (such as for migraine) or MAOIs. ^{32,36,37}
Celexa (citalopram) Effexor (venlafexine) Lexapro (escitalopram) Remeron (mirtazapine) Wellbutrin (bupropion) Zoloft (sertraline) Zyprexa (olanzapine)	Obsessive-compulsive disorder (OCD) Recurrent unwanted ideas, thoughts, impulses, or images (obsessions) that are repetitive and provoke anxiety, accompanied by behaviors or rituals (compulsions) to control the anxiety but which are recognized as excessive. ^{41,43}	
Fluvoxamine maleate (Luvox), approved for pediatric OCD. ³⁷	Other anxiety disorders Panic disorder —sudden attacks of terror, pounding heart, sweating, faintness. Post-traumatic stress disorder (PTSD) —startled response, irritability, aggression, violence. Social anxiety disorder (SAD) —extreme self-consciousness, fear of being watched, anxiety. Generalized anxiety disorder (GAD) —exaggerated worry or tension, insomnia; trembling, irritability. ⁴⁴	
Anafranil (clomipramine), approved for pediatric OCD. ³⁸		
Paxil (paroxetine) is not recommended for use in pediatric patients. ³⁹		
Risperdal (risperidone) is approved for pediatric mania or mixed episodes of bipolar I disorder. ⁴⁰		

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Drug	Symptoms *	What To Watch For **
Other psychotropic drugs used to manage ADD/ADHD, anxiety, or depression		
BuSpar (buspirone)	Symptoms of anxiety: shakiness, jumpiness, trembling, tension, muscle aches, tiredness; inability to relax, twitching, fidgeting, restlessness, startling; sweating, heart pounding; vigilance, apprehensiveness. ⁴⁵	Dizziness, nausea, headache, nervousness, lightheadedness, and excitement; slowness or sedative effect. ⁴⁵
Inderal (propranolol)	Anxiety, nervous tension; panic attacks; aggressive behavior.	Insomnia, excessive tiredness, nausea, vomiting, diarrhea, rash; difficulty breathing, fever, sore throat, swelling of feet or hands, slow heartbeat, chest pain. ⁴⁷
Wellbutrin, Zyban (bupropion)	Major depressive disorder. ⁴⁶	Agitation, anxiety, insomnia; hypertension; possible hallucinations or delusions. Weight loss. Dose-related risk of seizure. ⁴⁶
Effexor (venlafaxine)	Depression, as defined above.	Decreased appetite; headache, nausea, diarrhea; drowsiness, insomnia, sweating, dry mouth, dizziness, restlessness. Suicidality; serotonin syndrome. ^{48,49}
Atypical Antipsychotics used in psychotic disorders and dementia		
Risperdal (risperidone), is approved for pediatric schizophrenia and mania or mixed episodes of bipolar I disorder. ^{40,50}	Indicated for schizophrenia, bipolar disorder, mania; or mixed episodes.	Sleepiness, increased appetite, fatigue, respiratory infections; nausea, vomiting, dizziness, dry mouth. Hyperglycemia, diabetes mellitus; hypotension; cognitive and motor impairments. Rare: serious cardiac and neuromuscular effects. ⁵⁰
Abilify (aripiprazole) Clozaril (clozapine) Geodon (ziprasidone) Seroquel (quetiapine) Symbyax (olanzapine and fluoxetine) Zyprexa (olanzapine)	Other drugs may be prescribed off-label for certain conditions, or cases with multiple conditions occurring together.	
Mood Stabilizers used for bipolar disorder and mania		
Lithobid, Lithostat (lithium carbonate)	Recurrent episodes of depression, mania, and/or mixed symptom states; extreme shifts in mood, energy, and behavior; overly inflated self-esteem; decreased need for sleep; talkativeness, distractibility; hypersexuality; increased goal-directed activity or agitation. ^{9,10}	Nausea, drowsiness, dizziness, vomiting, abdominal pain; headache; tremor. Severe abdominal pain, nausea, and vomiting may be symptomatic of rare but severe pancreatitis and liver disease. ^{51,52}
Abilify (aripiprazole) Geodon (ziprasidone)		Do not take aspirin with Depakote. ⁵²
Depakote, Depakene (valproate)		
Drugs used with eating disorders, specifically bulimia nervosa and binge-eating disorder; occasionally in anorexia nervosa, after weight regain		
Prozac (fluoxetine)	Anorexia nervosa —Abnormal restriction of eating due to intense fear of gaining weight or becoming fat; resistance to maintaining weight at or above a minimally normal weight for the age and height. ⁵⁴	In anorexia, antidepressant medication is used only after weight regain is established. ⁵⁴
Zyprexa (olanzapine) ⁵³	Bulimia nervosa —Recurrent episodes of binge eating, followed by forced purging through self-induced vomiting, or use of laxatives, diuretics, enemas, or other medications; fasting; excessive exercise. ⁵⁴	Denial of illness, refusal to maintain treatment; may require hospitalization. ⁵⁴
Other SSRIs or SNRIs may be used, possibly other antipsychotics.	Binge-eating disorder —Uncontrolled eating (often rapidly and in great quantities) without forced purging or compensating behavior. ⁵⁴	Side effects: Impaired judgment, thinking, motor skills; anxiety, nervousness, insomnia; mania; agitation; decreased appetite; rash or hives; seizure; suicidality. ^{28,29,30,36}

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Mental Health Medications and the Risk of Suicide

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Mental Health Medications and the Risk of Suicide

In May 2007, the FDA expanded the requirement for “black box” warnings to include all antidepressants.

- Antidepressants, which are often effective in treating depression and other mental disorders, carry a risk of harmful side effects and complications. Some studies showed that antidepressants may cause suicidal thinking and behavior in children and adolescents. In the studies, children taking antidepressants had a 3.8% chance of developing suicidal thoughts or behavior, compared with 2.1% of children taking placebos.⁵⁵
- These results prompted the FDA in 2004 to require that all antidepressants include a warning, printed in bold type, framed in a black border—the “black box”—at the top of the paper insert.⁵⁶
- Antidepressants also will come with a medication guide that advises parents and caregivers about the risks and precautions.⁵⁶
- Considering the warning, why use antidepressants? The FDA label itself warns practitioners that the depression for which the medication is prescribed is the most important cause of suicidality.⁵⁷ A 2006 study showed that higher SSRI prescription rates were associated with lower suicide rates in children and adolescents.⁵⁸ The greater risk may be in doing nothing.⁵⁵

A child or adolescent taking antidepressant medication should be closely monitored for any changes in behavior, particularly when medication is initiated, or when dosing is changed or discontinued. Antidepressant therapy should not be stopped all at once but rather discontinued gradually, on a tapering schedule, under the physician's guidance.⁵⁹

Changes to watch for include worsening depression, emergence of suicidal thinking or behavior, or unusual behavior, such as sleeplessness, agitation, or withdrawal from normal social situations.⁵⁹

Suicidal thinking, feeling, and behaviors are core symptoms of depression; consequently, there is no way to know whether suicidal symptoms that develop during treatment are due to the underlying illness or the medication.⁵⁷

An inverse relationship appears to exist between diagnoses of pediatric depression with prescriptions for SSRI antidepressants on one hand, and rates of suicide in children and adolescents on the other.⁶⁰ Before SSRI antidepressants were introduced, the adolescent suicide rate tripled in two decades. When prescriptions for SSRI antidepressants increased for adolescent depression, suicide rates declined for a decade.⁵⁵ In the two years following the October 2004 FDA advisory, significant reductions in diagnosis of pediatric depression,⁶¹ and decreases in antidepressant prescriptions for children and adolescents were found,^{57,62} and these decreases were associated with increases in suicide rates in the same group.⁶⁰

Although depression and suicidal thinking are significant risk factors for suicide, depression in patients in a 2004 fluoxetine study improved four times as often as suicidality developed.⁵⁵ The benefits of antidepressants appear to be much greater than risks from suicidal thinking or behavior.⁶³

Medication Administration in the School

- Forty-nine states have state-level school health policies. Of those, 36 states have mandatory or recommended policies concerning administration of prescription medications at school. Ten states specifically address administration of psychotropic drugs.⁶⁴
- Control of prescription medications is particularly important in the school. Medications administered at school should be taken in the presence of the school nurse or her designate.⁶⁵
- Peers and family members are the leading sources of prescription drugs for illicit use by adolescents.⁶⁶
- Students who use their prescription medications as prescribed are at a lower risk for probable drug abuse than individuals who have nonmedical use, or both medical and nonmedical use of prescription medications.⁶⁶
- In 2003, the annual prevalence of illegal use of Ritalin was reported as 2.6% among 8th graders, 4.1% among 10th graders, and 4.0% among 12th graders.⁶⁷ In 2006, the annual illegal use among 8th graders remained the same, in 10th graders use declined to 3.6%, and among 12th graders illegal use increased to 4.4%.⁶⁸
- One survey of more than 44,000 high school students found that nearly 7% reported having used methylphenidate (Ritalin) illicitly at least once and 2.5% reported using it monthly or more often.⁶⁵

Psychotropic Drugs and Children

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The Five Rights of medication administration

- The **right** patient
- Receives the **right** drug
- In the **right** dose
- By the **right** route
- At the **right** time.

The Role of Schools: What to know, how to help^{64,66,69,70,71}

The FDA's medication guidance does not prohibit the use of antidepressants in pediatric populations but urges caution in administration and vigilance in monitoring.

- Obtain from your state and local governments, and Board of Education the specific rules for medication storage and administration. (See box.)
- Get to know the FDA resources on medications available on the FDA Web site, and be aware of public health advisories issued by the agency.
- Be aware of the possible side effects of the drugs being administered; learn to recognize symptoms of missed doses or overdosage. If you observe any of the behavioral warning signs—worsening illness, or agitation, irritability, suicidality, and unusual changes in behavior—contact the physician or parent immediately.
- Ask parents to notify the school when dosing begins, any dosing changes are made, or medication is replaced or discontinued. These are the times when the student is most likely to experience changes or additional effects.
- Have an emergency plan for each student taking psychotropic medications, in case there is ever a need to use one. Familiarize every relevant staff member with warning signs of medication lapse, misuse, or abuse, and provide training on how to respond.
- Safeguard the privacy of students and protect them from any stigma that may be associated with their disorder or the administration of medications during school hours.

Procedures for Medication Safety^{69,70,71}

Prescription medications can be stored and distributed safely and securely at school. Certain procedures will provide the surest handling:

- Obtain appropriate authorization forms from physicians and parents.
- Ask parents to bring the medication to the school, rather than sending it with the student.
- Ensure that medication is in the original container, bearing the name of the student, the name of the medication, dosage and timing, the name and phone number of the prescribing physician, with a copy of the package insert.
- Review the MedGuide provided with some medications.
- Store medications in a properly secured, controlled space.
- Observe students taking medication, to ensure the dose is consumed.
- Keep accurate and complete records of all administration.

Resources

Government Resources

National Institute of Mental Health (NIMH)
6001 Executive Boulevard
Room 8184, MSC 9663
Bethesda, MD 20892-9663
301-443-4513
www.nimh.nih.gov

US Food and Drug Administration (FDA)
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville MD 20857-0001
888-INFO-FDA (888-463-6332)
<http://www.fda.gov/cder/drug/antidepressants/default.htm>

Non-Government Resources

Bright Futures
The American Academy of Pediatrics
141 Northwest Point Boulevard
Elk Grove Village, IL 60007-1098
847-434-4000
<http://brightfutures.aap.org/web/>

Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD)
8181 Professional Place, Suite 201
Landover, MD 20785
800-233-4050
www.chadd.org

Mental Health America
National Mental Health Association
2000 N. Beauregard Street, 6th Floor
Alexandria, VA 22311
Main: (703) 684-7722
Fax: (703) 684-5968
Toll free (800) 969-6642
<http://www.nmha.org/>

National Alliance on Mental Illness (NAMI)
Colonial Place Three
2107 Wilson Blvd., Suite 300
Arlington, VA 22201-3042
Main: (703) 524-7600
Fax: (703) 524-9094
<http://www.nami.org/>



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