CLINICAL CAPSULES

Tailor Teen Pregnancy Messages

Pregnant adolescents aged 12-17 years are more likely than 18- or 19-year-olds to report that their babies would enhance their relationships with others, and older teens are more likely to identify the challenges of teen motherhood, data collected from 247 girls who sought care at a prenatal clinic show.

Understanding the variations in pregnant girls' attitudes toward pregnancy can help health care providers target interventions, although the differences among age subgroups did not reach statistical significance, reported Cynthia Rosengard, Ph.D., of Rhode Island Hospital in Providence and her colleagues (Pediatrics 2006;118:503-10).

The adolescents completed questionnaires and interviews about the pros and cons of having a baby as a teen. Their mean age was 16.8 years, and data were collected over a 2-year period.

The girls reported stronger connections with others and a sense of responsibility and purpose that might discourage them from other risky behaviors as some advantages of teen pregnancy. Disadvantages included financial concerns, lack of preparedness for motherhood, changing life plans, and missing out on other teenage experiences.

Risky Sex in Black Teens

Black adolescents who report depressive symptoms are nearly four times more likely to report inconsistent condom use than are peers who were not depressed, Dr. Larry K. Brown of Brown University in Providence, R.I., and his colleagues reported.

A majority of 277 of the 415 adolescents (67%) reported using condoms in less than 75% of sexual activities, and 138 (33%) reported using condoms in at least 75% of sexual activities, after the investigators controlled for demographic factors including age, gender, and income (J. Adolesc. Health 2006 [Epub doi:j.jadohealth.2006.01.015]).

Although males reported more condom use than females overall, the 13 males who reported depressive symptoms were significantly less likely to report condom use than were those who were not depressed. The 26 girls who reported depressive symptoms also were less likely to report condom use at follow-up, but the difference was not statistically significant.

People younger than 25 years account for about half of all new HIV infections in the United States each year, and blacks represented about 50% of HIV cases diagnosed in the country in 2003. Interventions for depression could reduce risky sexual behaviors in the high-risk black adolescent population and prevent the development of more severe emotional disorders, the researchers noted.

'Regardless of the lower incidence of depressive symptoms among these youth compared with peers of other races, depressive symptoms had a major impact on HIV and STI risk by quadrupling the odds

Older adolescents (19-21 years) were less likely to use condoms consistently than those aged 18 years and younger.

of inconsistent condom use," they wrote.

Race, Gender Affect Meth Use

Nonmedical use of prescription stimulants and methamphetamine by adolescents aged 12-17 years is significantly associated with use of marijuana and other illegal drugs and also with the use of mental health services, a study of more than 17,000 teenagers shows.

To assess the risk factors for stimulant abuse in adolescents, Mindy A. Herman-Stahl, Ph.D., and her colleagues at RTI International reviewed data on adolescents from the 2002 National Survey of Drug Use and Health (NSDUH), an annual survey of the civilian, noninstitutionalized population aged 12 years and older (J. Adolesc. Health 2006;39:374-80).

Overall, adolescents who reported treatment for mental health problems during the year before the survey were more than one and a half times as likely to report either amphetamine use or nonmedical prescription stimulant use during the past year. Also, marijuana use was more than four times as likely among the methamphetamine users and more than twice as likely among the illicit stimulant users.

After controlling for demographic variables, methamphetamine use was more than twice as likely among girls vs. boys and significantly less likely among non-Hispanic blacks vs. non-Hispanic whites. There were no racial or gender differences linked to nonprescription stimulant use, but significant associations were found with high levels of family conflict and sensation-seeking behavior.

Methamphetamine use was associated with deviant behavior such as selling drugs and binge drinking, which suggests that adolescents who use methamphetamine may be more likely to be exposed to delinquent peers and dangerous environments, the researchers said.

The study was built on a project that received funding from Eli Lilly & Co.

SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY.
MISUSE OF AMPHETAMINE MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAR ADVERSE EVENTS.

INDICATIONS
ADDERALL XR® is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).
The efficacy of ADDERALL XR® in the treatment of ADHD was established on the basis of two controlled trials in children aged 6 to 12 one controlled trial in adolescents aged 13 to 17, and one controlled trial in adults who met DSM-IV® criteria for ADHD, along with extrapolation from the known efficacy of ADDERALL®, the immediate-release formulation of this substance.
CONTRAINDICATIONS

abuse. During or within 17 usp a business. WaRNINGS
Serious Cardiovascular Events
Sudden Death and Pre-existing Structural Cardiac Abnormalities or Other Serious Heart Problems
Children and Adolescents
Children and Adolescents
Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents we structural cardiac abnormalities or other serious heart problems. Although some serious heart problems alone carry an increase risk of sudden death, stimulant products generally should not be used in children or adolescents with known serious structucardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may pit them at increased vulnerability to the sympathomimetic effects of a stimulant drug (see CONTRAINDICATIONS).

Adults

**The Contraction of the Contra

Authough the role of stimulants in these adult cases is also unknown, adults taking stimulant drugs at usual doses for ADHD. Although the role of stimulants in these adult cases is also unknown, adults have a greater likelihood than children of having serious structural cardiac abnormalities, action(myopathy, serious heart hythm abnormalities, coronary artery disease, or other serious cardiace problems. Adults with such abnormalities should also generally not be treated with stimulant drugs (see CONTRAINDICATIONS). Hypertension and other Cardiovascular Conditions

Stimulant medications cause a modest increase in average blood pressure (about 2-4 mmHg) and average heat rate rate (about 3-6 lpm) [see ADVERSE VENTS], and individuals may have larger increases. While the mean changes alone would not be expected to have short-term consequences, all patients should be monitored for larger changes in heart rate and blood pressure. Caution is indicated in treating patients should be monitored for larger changes in heart rate and blood pressure. Caution is indicated in the reating patients should be monitored for larger changes in heart rate and blood pressure. Caution is indicated in the reating patients should be monitored for larger changes in heart rate and blood pressure. Caution is indicated in the reating patients should be monitored for larger changes in heart rate and blood pressure. Caution is indicated in the reating patients should be monitored for larger changes in heart rate and blood pressure. Caution is indicated in the reating patients should be monitored for larger changes in heart rate and blood pressure. Caution is indicated in the reating patients should be monitored for larger changes. While the mean changes alone would reade in the monitored for larger changes in heart rate and blood pressure. Caution is patient to the committee of cardiac disease (a.g. electrocardiogram), heart failure, recent myocardial infanction, or ventricular arrhythmia (see Controlations). Assessing Draffication in findings

-Existing Psychosis inhistration of stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with existing psychotic disorder.

polar Illness ritcular care should be taken in using stimulants to treat ADHD patients with comorbid bipolar disorder because of concern I ssable induction of mixed/manic episode in such patients. Prior to initiating treatment with a stimulant, patients wi morbid depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder, su reening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. nergence of New Psychotic or Manic Symptoms.

of stimulant-teated patients compared to 0 in placebo-treated patients.

Aggression
Aggression
Aggressive behavior or hostility is often observed in children and adolescents with ADHD, and has been reported in clinical radias and the postmarketing experience of some medications indicated for the treatment of ADHD. Although there is no systematic evidence that stimulants cause aggressive behavior or hostility, patients beginning treatment for ADHD should be monitored for the appearance of or worsening of aggressive behavior or hostility.
Long-Term Suppression of Growth
Careful follow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or non-medication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicate children (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7 kg less growth in weight over 3 years), without evidence of growth rebound during this period of development. In a controlled trial of ADDERALL XR* in adolescents, mean weight change from baseline within the initial 4 weeks of therapy was -1 libs. And -2.8 lbs., respectively, for patients receiving 10 mg and 20 mg ADDERALL XR*. Higher doses were associated with greater weight loss within the initial 4 weeks of treatment. Published data are inadequate to determine whether chronic use of amphetamines may cause a similar suppression of growth, however, it is anticed that they will likely have this effect as well. Therefore, growth should be monitored during treatment with stimulants, and patients who are not growing or gaining weight as expected may need to have their treatment interrupted.

Visual Disturbance
Visual Disturbance
Visual Maccommodation and blurring of vision have been reported with stimulant treatment
PRECAUTIONS

Visual Disturbance of Secures. In the presence of secures, the drug should be prescribed or dispensed at one time in order to minimize the prescribed or dispensed at one time in order to minimize the prescribed prescribed or dispensed at one time in order to minimize the prescribed prescribed or dispensed at one time in order to minimize the prescribed prescribed or dispensed at one time in order to minimize the prescribed prescribed prescribed prescribed to dispensed at one time in order to minimize the prescribed prescribed prescribed prescribed to the prescribed or dispensed at one time in order to minimize the prescribed prescribed prescribed prescribed to the prescribed prescribed to the prescribed prescribed to the prescribed prescribed used of stimulant medications. Information for tics and fourette's syndrome in children and their families should prescribe use of stimulant medications. Information for Patients: Ampleatanies and impleatanies should prescribe used of stimulant medications. Information for Patients: Ampleatanies and impleatanies and prescribed prescribed used accordingly. Drug Interactions: Acidifying agents—assortion of ampleatanies (used the prescribed pres

30 mg/kg/day in male finue, 19 mg/kg/day (child] on a mg/mbody surface area basis.

Amphetamine, in the enantiomer ratio present in ADDERALL* (immediate-release) (d- to l- ratio of 3:1), was not clastogenic in the mouse bone marrow micronucleus test in wivo and was negative when tested in the E. col/component of the Ames test in witro. d.l-Amphetamine (1-1 enantiomer ratio) has been reported to produce a positive response in the mouse bone marrow micronucleus test, an equivocal response in the Ames test, and negative responses in the in witro sister chromatid exchange and chromosomal aberration assays.

Amphetamine, in the enantiomer ratio present in ADDERALL* (immediate-release) (d- to l- ratio of 3:1), did not adversely affect fertility or carly embryonic development in the rat at doses of up to 20 mg/kg/day (approximately 5 times the maximum recommended human dose of 30 mg/day on a mg/m² body surface area basis).

Pregnancy, Pregnancy, Category C. Amphetamine, in the enantiomer ratio present in ADDERALL* (d- to l- ratio of 3:1), had no Pregnancy, Pregnancy Category C. Amphetamine, in the enantiomer ratio present in ADDERALL* (d- to l- ratio of 3:1), had no state of the produce of t

There are no adequate and well-controlled studies in pregnant women. There has been one report of severe congenital bony deformity, tracheo-esophageal fistula, and anal atresia (valer association) in a baby born to a woman who took dextroampler amine sulfate with lovastatin during the first trimester of pregnancy. Amphetamines should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nonteratogenic Effects: Infants born to mothers dependent on amphetamines have an increased risk of premature delivery and low birth weight. Also, these infants may experience symptoms of withdrawal as demonstrated by dysphoria, including apitation, and significant lassitude.

**Usage in Nursing Mothers:* Amphetamines are excreted in human milk. Mothers taking amphetamines should be advised to refrain from unising.

3 years of age. **Geriatric Use:** ADDERALL XR® has not been studied in the geriatric population.

3) years of age.

Gertafric Use: ADDERALL XR® has not been studied in the geriatric population.

ADVERSE EVENTS

Hypertension: [See WARNINGS section] In a controlled 4-week outpatient clinical study of adolescents with ADHD, isolated systolic blood pressure elevations: 215 mmHg were observed in 764 (11%) placebo-treated patients and 77100 (7%) patients receiving ADDERALL XR® 10 or 20 mg. Isolated elevations in diastolic blood pressure ≥ 8 mmHg were observed in 1664 (25%) placebo-treated patients and 227100 (22%) ADDERALL XR® retreated patients. Similar results were observed all higher doses. In a single-dose pharmacokinetic study in 23 adolescents, isolated increases in systolic blood pressure above the upper 95%. If or age, gender and staturely were observed in 2717 (12%) and 823 (35%), subjects administered 10 mg and 20 mg ADDERALL XR®, respectively. Higher single doses were associated with a greater increase in systolic blood pressure. All increases were transient, appeared maximal at 20 4 hours post dose and not associated with symptoms. The premarketing development program for ADDERALL XR® included appeared in 135 anticipants in clinical trials. The premarketing development program for ADDERALL XR® included in the discussion that follows. Adverse reactions were appeared to the discussion that follows. Adverse reactions were appeared to the discussion that follows. Adverse reactions were adverse events during exposure were obtained primarily by general inquiry and recorded by clinical investigators using terminology of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse events without first grouping similar types of events into a smaller number of standardized event categories. In the tables and listings that follow, COSTART terminology has been used to classify reported adverse events. The stated frequencies of adverse events without first grouping similar types of events into a smaller number of standardized event cat

ADDERALL XR° for 12 months of more.				
Adverse event	% of pediatric patients	l		
	discontinuing (n=595)	ı		
Anorexia (loss of appetite)	2.9	ı		
Insomnia	1.5	ı		
Weight loss	1.2	ı		
Emotional lability	1.0	ı		
Depression	0.7			

urues, stroke.

II: Dryness of the mouth, unpleasant taste, diarrhea, constipation, other gastrointestinal disturbances. Anorexia and y occur as undesirable effects.

Allernic: Urticaria. rash, hypersensitivity reactions

Table 1 Adverse Events Reported by More Than 1% of Pediatric Patients
Receiving ADDERALL XR* with Higher Incidence Than on Placebo in a
584 Patient Clinical Study
Syndrome and twice and sevents are sevents and sevents and sevents are sevents and sevents are sevents and sevents are

Body System	Preferred Term	ADDERALL XR® (n=374)	Placebo (n=210)
General	Abdominal Pain (stomachache)	14%	10%
	Accidental Injury	3%	2%
	Asthenia (fatigue)	2%	0%
	Fever	5%	2%
	Infection	4%	2%
	Viral Infection	2%	0%
Diaestive	Loss of Appetite	22%	2%
System	Diarrhea	2%	1%
•	Dyspepsia	2%	1%
	Nausea	5%	3%
	Vomiting	7%	4%
Nervous System	Dizziness	2%	0%
	Emotional Lability	9%	2%
	Insomnia	17%	2%
	Nervousness	6%	2%
Metabolic/Nutritional	Weight Loss	4%	0%

Metabolic/Nutritional	Weight Loss	4%	0%		
Table 2 Adverse Events Reported by 5% or more of Adolescents Weighin ≤ 75 kg/165 lbs Receiving ADDERALL XR® with Higher Incidence Than Placebo in a 287 Patient Clinical Forced Weekly-Dose Titration Study*					
Body System	Preferred Term	ADDERALL XR® (n=233)	Placebo (n=54)		
General	Abdominal Pain (stomachache)	11%	2%		
Digestive System	Loss of Appetite b	36%	2%		
Nervous System	Insomnia ^b Nervousness	12% 6%	4% 6%²		
Metabolic/Nutritional	Weight Loss b	9%	0%		
Appears the same due to Dose-related adverse eve					

reported by 2% to 4% of adolescent patients receiving ADDERALL XR® with a lincidence than patients receiving placebo in this study: accidental injury, ast (fatigue), dry mouth, dyspepsis, emotional lability, nausea, somnoience and were "included doses up to 40 mg

-included doses up to 40 i	ng			
Table 3 Adverse Events Reported by 5% or More of Adults Receiving ADDERALL XR® with Higher Incidence Than on Placebo in a 255 Patient Clinical Forced Weekly-Dose Titration Study*				
Body System	Preferred Term	ADDERALL XR® (n=191)	Placebo (n=64)	
General	Asthenia Headache	6% 26%	5% 13%	
Digestive System	Loss of Appetite Diarrhea Dry Mouth Nausea	33% 6% 35% 8%	3% 0% 5% 3%	
Nervous System	Agitation Anxiety Dizziness Insomnia	8% 8% 7% 27%	5% 5% 0% 13%	
Cardiovascular System	Tachycardia	6%	3%	
Metabolic/Nutritional	Weight Loss	11%	0%	
Urogenital System	Urinary Tract Infection	n 5%	0%	
Note: The following events of	did not meet the criterion f	or inclusion in Tabl	a 3 hut war	

Manufactured for: Shire US Inc., Wayne, PA 19987 Made in USA For more information call 1-800-828-2088, or visit www.adderalixr.com. ADDERALL 'And ADDERALL XR' are registered in the US Patent and Trademark Office. Copyright @2006 Shire US Inc. 381 0107 010 ABFS18 **Shire**

-Heidi Splete