

Antidepressants

What Parents Think What Research Says What We Are Doing About It

Answers to whether or not antidepressants are safe are not simple. Like many prescription drugs, these psychiatric medications come with a list of side effects that must be balanced with the drug's treatment benefits. Since 2004, the risk-benefit balance for antidepressants has become harder to weigh. On September 14, 2004, a Food and Drug Administration (FDA) panel voted 18 to 5 to require manufacturers of all antidepressants to add black box warnings to their product labeling. The warnings cite short-term studies in children and adolescents that showed an increased risk in suicidal thinking and behavior.

"Thoughts of suicide and suicide attempts are the most frightening reported adverse effects of antidepressant use," says Jeff Bridge, PhD. "These engendered the most negative publicity and have been associated with a decrease in use of antidepressants in children and adolescents." Investigators in the Center Biobehavioral Health and the Center for Innovation in Pediatric Practice, including Dr. Bridge, are working together to provide clarity and develop solutions to the antidepressants controversy.

PARENTS SENSE THE BENEFIT AND THE RISK

Parents perceive antidepressant medications as beneficial but risky according a recent study. Nationwide Children's psychologist Jack Stevens, PhD, led one of the first studies of its kind to measure parents' perceptions of the risks and benefits of medications by their children, especially antidepressants. "A clear understanding of common parental attitudes is essential for care providers who interact with parents of children and adolescents," said Dr. Stevens, who is also a principal investigator in the Center for Biobehavioral Health at The Research Institute.

Five hundred one parents visiting Nationwide Children's Hospital mental health centers were asked to complete a questionnaire titled "What Parents Think about Behavioral Health Care for Kids." The questionnaire assessed demographic characteristics, treatment history, and attitudes toward psychotherapy.

A substantial portion of parents reported concerns regarding the safety of antidepressants; many parents perceived antidepressants as precipitating suicidal ideation. African American parents often had less favorable views of antidepressants relative to parents of other ethnicities. Also, parents expected a higher level of physician monitoring of pediatric antidepressant use than is offered and available in most communities.

RESEARCH SAYS BENEFITS OUTWEIGH THE RISKS

While Dr. Stevens' research has focused on perceived risk and benefit, Dr. Bridge and colleagues at the University of Pittsburgh School of Medicine sought to assess reported risk and benefit.

They looked at the outcomes of randomized, controlled and clinical trial reports of antidepressants used to treat children and adolescents younger than 19 years for major depressive disorder, obsessive-compulsive disorder and non-OCD anxiety disorders.

The study found that for every 100 children and adolescents younger than 19 years who were treated with antidepressants,



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about one child would have thoughts of suicide or attempt suicide beyond the risk associated with the condition itself. These findings were slightly lower than an FDA study that included seven fewer trials.

“Our findings mean that antidepressants should be considered as a first-line treatment option for pediatric depression and anxiety disorders, with the recognition that these medications are more effective for anxiety disorders, including OCD and modestly effective for MDD,” said Dr. Bridge. “We recognize that there are other therapies, aside from antidepressants, to treat pediatric depression and anxiety disorders including psychotherapies,” said Bridge. “While there is a small overall increased risk of suicidal thoughts and attempts with antidepressants, the risk-benefit ratio appears favorable.”

TECHNOLOGY TO IMPROVE CARE AND ASSUAGE FEARS

Despite the benefits of antidepressant treatment, the FDA and parents both insist on a higher level of physician monitoring than seems to be logistically available in most communities. According to a 2006 American Academy of Pediatrics policy statement, community mental health resources have diminished or disappeared in some regions, resulting in critical shortages of inpatient and outpatient mental health services for children.

In light of this shortage and in order to address the perceived and documented risks tied to antidepressants, faculty in the Center for Innovation in Pediatric Practice and the

Department of Psychiatry at The Ohio State University have developed a system to monitor pediatric outpatients who are taking antidepressants. Pharmacy Safety Tracking (PhaST), which is currently being piloted within Nationwide Children's Biobehavioral Health Clinic, makes automated telephone calls to teenage patients or parents of younger children who are taking antidepressants. The automated system asks research-based assessment questions intended to screen for adverse medication events. Patients answer these simple yes or no questions and if PhaST detects a possible event, such as a suicidal thought, a physician is alerted to call the patient and conduct a telephone interview to triage the risk. If the clinician judges that there is a possible adverse event, the doctor alerts an on-call psychiatrist by secure email.

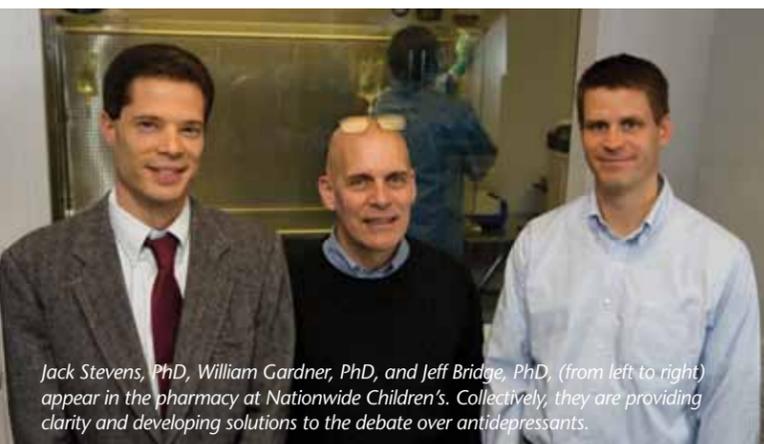
“Early results suggest that the PhaST system will meet current guidelines for recommended patient contacts to check antidepressant safety,” said William Gardner, PhD, principal investigator in the Center for Innovation in Pediatric Practice and the project's lead investigator.

Disclosure: Dr. Stevens is a shareholder in Wyeth.

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Jack Stevens, PhD, William Gardner, PhD, and Jeff Bridge, PhD, (from left to right) appear in the pharmacy at Nationwide Children's. Collectively, they are providing clarity and developing solutions to the debate over antidepressants.