Cardiac Risk of Stimulants for Children With ADHD:

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Of particular utility in the position statement is a checklist for identifying children who are at risk for sudden death, independent of ADHD or stimulant drug treatments.

New guidelines to assess cardiac risk before using stimulant medication in children and adolescents with attention-deficit/hyperactivity disorder (ADHD) were published concurrently in 3 Canadian medical society journals in November. Publication of these guidelines coincided with an FDA announcement of a delay in a US epidemiological study of the potential cardiovascular risk.

The FDA had joined with the Agency for Healthcare Research and Quality (AHRQ) to sponsor a large epidemiological study after a provocative online study report in June in the *American Journal of Psychiatry* had suggested an association between the use of stimulant medication and sudden death. Although the FDA-AHRQ-sponsored study results were to be completed in late 2009, the FDA indicated in November that the results are now expected by August 2010.

According to the FDA, the study, called the Multicenter Observational Cohort Study to Assess the Cardiovascular Risks of Medications Prescribed for Attention Deficit and Hyperactivity Disorder, “is delayed because of technical challenges and logistic difficulties.”

The FDA-AHRQ-sponsored study is collecting data from more than 500,000 ADHD medication users and 1 million nonusers across 12 different health plans, in addition to reviewing approximately 2000 medical records from hundreds of hospitals. The study reported in the *American Journal of Psychiatry*, which had also been funded by the FDA as well as by the NIMH, compared the use of stimulant medication in 564 healthy children who had died suddenly with the use of stimulant medication in 564 children who had died in car accidents. The researchers, Madelyn Gould, PhD, MPH, and colleagues in the division of child and adolescent psychiatry at the New York State Psychiatric Institute, had concluded that there may be an association between medication use and sudden death in apparently healthy children.

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The FDA review of the Gould study noted that several limitations in the methodology precluded a more certain conclusion. These included the determination of stimulant medication use many years after each child’s death, differences in causes of death, and low frequency of stimulant use in both groups. While the FDA-AHRQ–sponsored epidemiological study is ongoing, the FDA advised practitioners in its November statement to follow all current prescribing information for use of these medications, including:

• Taking a medical history for cardiovascular disease in the child and family
• Performing a physical examination, with special focus on the cardiovascular system
• Considering obtaining further tests, such as screening electrocardiography and echocardiography, if the history or examination suggests an underlying risk for, or the presence of, heart disease

**Canadian recommendations**

The new treatment guidelines in Canada were offered in a joint position statement by the Canadian Paediatric Society, the Canadian Academy of Child and Adolescent Psychiatry, and the Canadian Cardiovascular Society. The joint committee reviewed Health Canada data on adverse reactions in children who used stimulant medications in addition to FDA data and peer-reviewed literature. The Canadian statement is consistent with current FDA-approved labeling in advocating for a thorough history and physical examination before treatment with stimulant medication is started. The statement emphasizes the importance of identifying risk factors for sudden death but stops short of recommending routine ECG screening or cardiology consultation, unless indicated by findings from the history or physical examination.

Of particular utility in the position statement is a checklist for identifying children who are potentially at risk for sudden death, independent of ADHD or the stimulant medication treatments. In the history, for example, these include palpitations brought on by exercise or fainting, or seizures with exercise, startle, or fright. Possible physical indicators include hypertension, a sternotomy incision, or cardiac murmur.

In addition to indicating a consensus among 3 Canadian medical societies, the joint position statement is in agreement with the FDA on the necessity for additional research, including the ongoing epidemiological study. The position statement ranks evidence for each of its recommendations and finds that the available data and studies do not rise above a rank of “C.” “A” and “B” are reserved, respectively, for multiple randomized clinical trials or meta-analyses, and for a single randomized clinical trial or large nonrandomized studies.

“Although recommendations are based on the best evidence currently available,” the position statement notes that “the committee further agrees that more research on this subject is necessary to optimize the approach to this common clinical scenario.”

**References:**


**Links:**

[1] [http://www.physicianspractice.com/authors/kenneth-j-bender-pharmd-ma](http://www.physicianspractice.com/authors/kenneth-j-bender-pharmd-ma)