No increase in severe cardiovascular events for children, adolescents taking ADHD medications

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Despite recent concerns that medications for attention deficit hyperactivity disorder (ADHD) could increase the risk of cardiovascular events in children and adolescents, an observational study conducted by researchers at the University of Pennsylvania School of Medicine and HealthCore Inc. finds they are no more likely to die from a severe cardiovascular event than those who do not take the drugs. The findings, published online in the journal *Pediatrics,* provide the first analysis of such events in a large population of children and adolescents receiving ADHD medications compared to non-users.

"These data provide reassurance that the thing most concerning – death – is not any higher in users of ADHD medications than non-users," says senior author Sean Hennessy, PharmD, PhD, an associate professor of Epidemiology at Penn. "For kids who will benefit from ADHD treatment, the potential risk of a cardiovascular event should not dissuade parents or caregivers from giving a child or adolescent these drugs."

An estimated 2.7 million or 4.8 percent of all children in the U.S. ages 4-17 took ADHD medications in 2007, the most recent year for which data are available. After previous studies found drugs to treat ADHD can lead to increased heart rate and blood pressure in children, Hennessy's group turned to a large database of patient records to see if patients who recently began taking ADHD medications appeared any more likely to

suffer from sudden death, heart attack, or stroke.

For the study, researchers sifted through patient data contained in Medicaid databases from five states (CA, FL, PA, NY, OH) and the HealthCore Integrated Research Database, which contains historical and current medical and pharmacy claims data from more than 44 million enrollees in Blue Cross and Blue Shield plans in 14 states. Hennessy's group identified 241,417 patients ages 3-17 on ADHD medications and tracked their health records during the period they were on medication (a median of 135 days). The researchers then compared rates of sudden death, heart attack, and stroke in patients taking ADHD medications to those not taking medications who were of the same age, sex and from the same state over a median of 609 days.

The researchers found 28 deaths in the group exposed to ADHD medications (incidence 1.79 per 10,000 person-years) and 607 in the control group (incidence 3.00 per 10,000 person-years). Additionally, the researchers identified no cases of heart attack or stroke in the group who received ADHD medications and 11 cases in the unexposed group. Because the group of children and adolescents receiving ADHD medications had no validated reports of stroke and heart attack, researchers were unable to rule out relative increases in the rate of such events from use of the drugs.

"The fact that the rates of cardiovascular events that could be identified were very low is of interest because at least we can tell that we do not have an epidemic of such events in kids receiving ADHD drugs," Hennessy says. "If ADHD medications were causing an epidemic of cardiovascular events, we would expect to see it in this study."

"This is one of first answers but it won't be the last," Hennessy says, adding that since 2007, the U.S. Food and Drug Administration (FDA) and Agency for Healthcare Research and Quality (AHRQ) has been

looking into the potential cardiovascular risks of ADHD medications on children. "Until the results of the FDA study become public, this study should provide reassurance to parent and caregivers that ADHD drugs are safe from cardiovascular perspective."

Provided by University of Pennsylvania School of Medicine