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Study finds anticonvulsant drug poses greater birth-defect risk than suspected

Risk with valproate four time greater than with alternative medications

BOSTON - March 21, 2005 - Use of the anticonvulsant drug valproate during pregnancy may pose a significantly great risk of birth defects than does use of other antiseizure medications. In the March 22 issue of *Neurology*, researchers from the North American AED (Antiepileptic Drug) Pregnancy Registry at Massachusetts General Hospital (MGH) report that women taking valproate alone had a fourfold increased risk of having a child with a major malformation, compared with the risk among women taking other anticonvulsants.

"The basic message for women who take valproate is to plan ahead if they want to have children. Discuss the risks with their physician and consider taking alternative drugs," says Lewis Holmes, MD, chief of the [Genetics and Teratology Unit](#) at MassGeneral Hospital for Children, director of the registry and senior author of the *Neurology* paper.

Sold in the U.S. under the brand names Depakote and Depakene, valproate is used to treat seizures, migraines and such psychiatric disorders as bipolar disorder. Earlier studies have suggested a potential risk of birth defects, primarily neural tube defects such as spina bifida, but none had definitively established the level of risk and the types of malformations that most frequently occur.

The [North American AED Pregnancy Registry](#) was established in 1996 and has enrolled more than 4,000 women who took anticonvulsant drugs during pregnancy. The current study analyzed information from 149 women who took only valproate while pregnant during the years 1997 to 2003. Of those 149 women, 16 had infants with major birth defects. Three infants had spina bifida, and a wide variety of malformations was seen in the others, including developmental delays.

While the risk level among women taking valproate was 10.7 percent, the risk for women in the registry who took other anticonvulsants as single-drug therapy was only 2.9 percent. In a comparison group of infants whose mothers had not taken an anticonvulsant drug, the frequency of major malformations in infants born to women at Brigham and Women's Hospital was 1.6 percent.

"This is the first indication to many neurologists that they should focus on more than the risk of spina bifida with this drug," says Holmes. "Many physicians have just advised their patients taking valproate to make sure to take folic acid to prevent neural tube defects; but the women in our study who had children with spina bifida or other malformations had all taken the recommended dose of folic acid." Holmes is a professor of Pediatrics at Harvard Medical School.

Co-authors of the *Neurology* report are first author Diego Wyszynski, MD, PhD, of Boston University School of Medicine and Public Health; Maya Nambisian, MPH, and Triptaa Surve, MPH, of Harvard Medical School; Caitlin Reilly Smith, MPH, of the MGH, and Rachel Alsdorf of Boston University.

The largest hospital-based pregnancy registry of any kind, the North American AED Pregnancy Registry is supported by grants from Abbott Laboratories, Elan Pharmaceuticals, GlaxoSmithKline, Novartis, Ortho-McNeil and Pfizer Pharmaceuticals. More information is available at www.aedpregnancyregistry.org or by calling toll-free 888-233-2334.

[MassGeneral Hospital for Children](#), the pediatric service of Massachusetts General Hospital, is the oldest provider of pediatric services in Boston. It is consistently listed in the *U.S. News and World Report* Guide to America's Best Hospitals and was ranked number 17 in the 2004 edition. Through its growing

network of community-based facilities and pediatricians, the hospital's excellent care is conveniently accessible to families throughout the region.

Massachusetts General Hospital, established in 1811, is the original and largest teaching hospital of Harvard Medical School. The MGH conducts the largest hospital-based research program in the United States, with an annual research budget of more than \$450 million and major research centers in AIDS, cardiovascular research, cancer, cutaneous biology, medical imaging, neurodegenerative disorders, transplantation biology and photomedicine. In 1994, MGH and Brigham and Women's Hospital joined to form Partners HealthCare System, an integrated health care delivery system comprising the two academic medical centers, specialty and community hospitals, a network of physician groups, and nonacute and home health services.

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