



Autism Study

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current as of July 22, 2009.

JAMA. 2009;302(4):375 (doi:10.1001/jama.2009.1046)

<http://jama.ama-assn.org/cgi/content/full/302/4/375>

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Autism Study

The National Institutes of Health (NIH) is funding a large prospective study that may shed light on genetic and environmental factors that contribute to autism spectrum disorders, as well as identify early biological signs of autism (<http://www.earlistudy.org/>).

The Early Autism Risk Longitudinal Investigation (EARLI) will enroll as many as 1200 mothers of children with autism from the start of a subsequent pregnancy and then monitor the resulting children until the age of 3 years. The women will be asked to complete surveys and provide biological samples; such samples also will be collected from the children, who will undergo periodic assessments for autism.

Several institutions in Pennsylvania, California, and Maryland will participate. A \$14 million grant from the NIH and a \$2.5 million grant from Autism Speaks, an advocacy group for children with autism and their families, are funding the study.

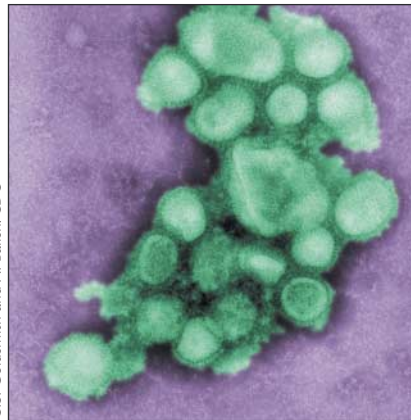
H1N1 Vaccine

Several companies are developing a vaccine for novel influenza A H1N1 virus, and clinical trials of the vaccine are expected to begin soon, according to the national Centers for Disease Control and Prevention (CDC).

At a press briefing June 11, Anne Schuchat, MD, interim deputy director for the CDC's Science and Public Health Program, said that the US government has launched an effort to develop a vaccine against this currently circulating strain, and that the vaccine was expected to be available this fall. In fact, Novartis AG, GlaxoSmithKline PLC, and Baxter International have all announced they have begun the process.

The US Department of Health and Human Services has set aside \$1 bil-

lion for the development and manufacture of such a vaccine. Schuchat cautioned that the CDC has not yet decided whether US individuals should be vaccinated. But having the vaccine on hand



Several companies are working on a vaccine against the influenza A H1N1 virus.

will allow a quick rollout if it is deemed necessary, she said; if not, the vaccine components will be stored for possible reformulation for future use.

Leukotriene Inhibitor Warning

The US Food and Drug Administration is asking manufacturers of leukotriene inhibitors to add warnings about serious psychiatric adverse events to the drugs' labels. Such drugs are approved for the treatment of asthma and allergic rhinitis.

Since 2007, Merck & Co, Inc, the manufacturer of montelukast, voluntarily added tremor, depression, suicidality, and anxiousness to the list on the drug's label of postmarketing adverse events that have been reported in patients taking the drug. Now, the agency wants a stronger caution on the label of montelukast regarding psychiatric adverse events, as well as similar changes to the labels of asthma drugs zafirlukast and zileuton, which have a similar method of action.

The agency has received postmarketing reports of agitation, aggres-

sion, anxiousness, abnormal dreams, hallucinations, depression, insomnia, irritability, restlessness, suicidal thinking and behavior (including suicide), and tremor in patients taking these drugs. Physicians and patients should be aware of such potential adverse events; if such neuropsychiatric symptoms arise, patients should discuss them with their physician and the physician should consider discontinuing use of the drug, the FDA advised (<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm165489.htm>).

New Inflammatory Disorder

An international team of scientists, including several from the National Institutes of Health, have identified a new autoinflammatory disease.

The scientists identified 9 children from 6 families who were homozygous for mutations in *IL1RN*, a gene in the interleukin 1 (IL-1) pathway, and who developed severe skin and bone inflammation shortly after birth (Aksentijevich I et al. *N Engl J Med*. 2009; 360[23]:2426-2437). The researchers proposed naming the disorder deficiency of the interleukin 1-receptor antagonist (DIRA).

The protein product of *IL1RN* inhibits IL-1, and unchecked IL-1 causes life-threatening inflammation in these patients, according to the scientists. Five of 6 surviving patients treated with anakinra, a recombinant IL-1-receptor antagonist, experienced remission; the patient who did not respond to the drug had chromosomal deletions that included *IL1RN*, the authors report.

The authors also recommend screening newborns for this autosomal recessive genetic disorder in Newfoundland, the Netherlands, and Puerto Rico, where this allele is more common, possibly due to a founder effect.—Bridget M. Kuehn