CDC to Monitor Seasonal Flu Vaccine for Seizures

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FROM A MEETING OF THE CDC'S ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

ATLANTA – Reports of febrile seizures in young children in Australia and New Zealand following vaccination with a 2010-2011 seasonal trivalent influenza vaccine have the Centers for Disease Control and Prevention watching closely for signs of trouble in the United States.

The CDC will collaborate closely with international scientists, partners, and regulatory authorities, and will collaborate on animal pyrogenicity studies using the vaccine in question, Dr. Michael McNeil reported at the meeting..

Furthermore, existing vaccine safety data systems currently in place for the 2009 H1N1 monovalent vaccine – which is included in the 2010-2011 seasonal vaccine, will be used to monitor for seizures and febrile seizures following vaccination with the seasonal vaccine. These systems, including the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD), are capable of detecting signals for seizure risk early in the course of the vaccination season, said Dr. McNeil of the CDC's immunization safety office.

The reports of seizures in Australia earlier this year led the chief medical officer there to suspend use of the 2010-2011 seasonal trivalent influenza vaccine for all children younger than 5 years. Prior to that suspension, the recommendation for all of Australia was that seasonal vaccination be administered to children with chronic medical conditions who were aged 6 months to 18 years. In Western Australia, vaccination was recommended for all children aged 6 months to 5 years.

The predominant vaccine used in Australia was trivalent Fluvax Junior, manufactured by the Australia-based biopharmaceutical company CSL Ltd., which dominates the market there; CSL vaccine accounted for nearly all trivalent seasonal vaccine distributed there by late April. A preliminary investigation revealed a signal suggesting an increase in febrile seizures, mostly among children younger than 5 years in the 24 hours following vaccination, with an estimate of up to 9 cases per 1,000 vaccinated, compared with an estimate of fewer than 1 case per 1,000 vaccinated with the 2009 H1N1 monovalent vaccine alone, Dr. McNeil reported.

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To date, no biologic, clinical, or epidemiologic factors have been identified to explain the increase in febrile seizures following vaccination, and no abnormalities have been detected in the vaccine, he said.

Although New Zealand has suspended use of the CSL vaccine following the four reports of febrile seizures after vaccination with that product there, other countries in the Southern hemisphere that have childhood vaccination programs, including Argentina, Chile, and South Africa, have not reported febrile seizures, and the World Health Organization has received no reports of febrile seizures associated with other 2010-2011 seasonal influenza vaccines, including Vaxigrip (Sanofi-Aventis) and Influvac (Solvay Pharmaceticals Inc.).

Dr. McNeil noted that CSL vaccines have been used for those aged 18 years and older in the United States since 2007, and that a CSL vaccine was licensed for children aged 6 months and older in November 2009, although very few doses of that trivalent seasonal vaccine were distributed in the 2009-2010 influenza season.

VAERS data showed no cases of febrile seizures following administration of CSL's seasonal vaccine for children aged 6 months and older, and only four cases following administration of the CSL 2009 H1N1 monovalent vaccine, all of which occurred in adults. No signal was detected by VAERS or VSD for seizure following any 2009-2010 seasonal influenza vaccines or H1N1 vaccines, he said. ■