Large study reaffirms H1N1, seasonal flu vaccine safety

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Back in spring 2009, the H1N1 influenza virus crossed the U.S. border and raised concerns that it might cause a full-scale epidemic in the fall. The Food and Drug Administration worked with other Health and Human Services agencies and vaccine manufacturers to quickly develop, license and distribute a vaccine to protect the public from this particularly virulent strain of the flu.

However, alongside the public's concern about H1N1 were also fears that the rapid vaccine development would lead to unanticipated problems similar to the increased risk of Guillain-Barré syndrome that occurred with the 1976 swine flu vaccine.

A new study shows that those fears were unsubstantiated and reaffirms the safety of the seasonal flu and H1N1 influenza vaccines.

"In the 2009-2010 season, when everyone was concerned about H1N1 because it was so new," data analysis showed no increased risk for specific side effects, said Grace M. Lee, M.D., lead researcher. "This is very reassuring."

Lee is an assistant professor of population medicine and pediatrics at Harvard Pilgrim Health Care and Harvard Medical School. The study, which relied on data from the Centers for Disease Control's Vaccine Safety Datalink Project (VSD), appears online and in the August issue of the *American Journal of Preventive Medicine*.

At the start of the 2009-2010 flu season, the VSD Project began tracking data on a near-real time basis from eight medical organizations that together give care to 9.2 million children and adults. Each week, the organizations provided combined data for all immunizations, hospital admissions, emergency visits, outpatient encounters and diagnoses. Researchers then looked at the incidence of adverse events potentially associated with immunization, including Guillain-Barré syndrome, seizures, Bell's palsy, other neurologic conditions and allergic reactions to detect any possible problem early enough to prevent widespread occurrence.

The analysis found no elevated risk for any adverse event, including Guillain-Barré syndrome, a condition that causes varying degrees of muscle weakness.

In the course of the study, researchers found one "safety signal," an elevated incidence following the H1N1 vaccine of Bell's palsy, a condition in which the muscles on one side of the face become paralyzed and which often resolves over time. When researchers dug deeper and adjusted for the fact that Bell's palsy generally is more common during flu season — late fall through winter — they found no association between the H1N1 vaccine and an increased incidence of Bell's palsy.

Jon Abramson, M.D., chair of the pediatrics department at Wake Forest Baptist medical center and a member of the World Health Organization's Strategic Advisory Group of Experts on Immunization, said he hopes this study will further convince the public of the safety and benefits of the flu vaccine. While flu immunization rates hover just over 40 percent — much lower than the 90-plus percent he said he would like to see — rates have increased in recent years.

"We've been using the influenza vaccine for now close to 50 years and there's a tremendous amount of data that say it's safe," he said. However,

Abramson said that ongoing monitoring systems such as VDS are critical to detecting or preventing situations such as the increased incidence of Guillain-Barré syndrome associated with the swine flu vaccine.

“Every year they’re changing the virus strain and every year there’s some chance that a strain will cause a specific problem, like what happened in 1976,” Abramson said. He added that, except for what happened in 1976, studies indicate that Guillain-Barré syndrome occurs more often because of an infection by the flu virus itself, rather than from getting the vaccine. “The risk-benefit ratio is clearly in favor of the vaccine.”

More information: Lee GM, et al. H1N1 and seasonal influenza vaccine safety in the Vaccine Safety Datalink Project. *Am J Prev Med* 41(2), 2011.

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