

H1N1 Influenza A (Swine Flu) Alert Center

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No Adverse Events Reported So Far With H1N1 Influenza Vaccine

Fran Lowry

November 19, 2009 — No adverse events have been reported as yet from the H1N1 influenza vaccine, according to experts who are tracking the vaccine's safety through several postmarketing surveillance programs.

"So far we have no signals of concern in H1N1 vaccines nationally or internationally," Hector Izurieta, MD, MPH, from the US Food and Drug Administration Center for Biologics Evaluation and Research in Rockville, Maryland, told members of the FDA's Vaccines and Related Biological Products Advisory Committee yesterday.

Dr. Izurieta said concerns about the H1N1 vaccine's safety have prompted several passive and real-time safety surveillance enhancements to be put in place. This has resulted in stronger collaboration and communication among government agencies in the United States and worldwide, including Centers for Medicare & Medicaid Services, the Veterans Administration, Indian Health Services, and the World Health Organization.

Claudia Vellozzi, MD, MPH, from the Centers for Disease Control and Prevention (CDC)'s epidemiology and surveillance division in Atlanta, Georgia, reported that a total of 327,093 doses of H1N1 vaccine have been administered, according to CDC records, but that no potential association with signals have been identified.

No Signals, but Data Insufficient to Assess Safety

However, she added, "The 2009 H1N1 influenza vaccines have only recently begun to be administered, and the data are insufficient to assess safety of the vaccine to date, but there have been no signals."

Similar safety results are being seen with more than 2 million doses of seasonal influenza vaccine.

The US Department of Defense (DOD) has put into place 3 surveillance programs, said LTC Patrick Garman, PharmD, PhD, deputy director for scientific affairs, Military Vaccine Agency, Bethesda, Maryland.

These include enhanced surveillance of H1N1 vaccine safety in real time, or as close to real time as possible, among approximately 1.5 million military personnel who will be vaccinated during the 2009 to 2010 vaccination period.

"We just started this program November 2. We run through our database on Mondays, do the analysis, share the information with the vaccine safety data link with people at the CDC, they do a review, and we get the

results back on Tuesday with statistical information attached," Dr. Garman explained to the committee.

A second program will compare *International Statistical Classification of Diseases and Related Health Problems, Ninth Edition*, codes to check for any unanticipated adverse effects that might not have been thought of earlier, he said.

The DOD is also monitoring the safety effects of the H1N1 vaccine in pregnancy.

So far, "at 2 weeks and counting," more than 30,000 vaccinations have been administered to military personnel throughout the world, including Iraq, Afghanistan, South Korea, Europe, Kosovo, and Japan, and more than 500,000 doses have been distributed within the DOD. No high-priority outcomes such as Guillain-Barré syndrome have been identified.

The H1N1 vaccine is also being administered to DOD beneficiaries and to civilians who work for the DOD.

"I think we will end up vaccinating up to 3 million individuals in this program," Dr. Garman said. "So far, there have been no cases of adverse events to review, but the initial military vaccinees have not reached the end of their risk window."

Health Plans to Help With Surveillance

A novel H1N1 surveillance program is enlisting the help of large, national health plans to help track the safety of the vaccine.

The Post-Licensure Rapid Immunization Safety Monitoring (PRISM) system was described by Richard Platt, MD, from Harvard Pilgrim Health Care and Harvard Medical School, Boston, Massachusetts.

"Many H1N1 vaccine doses may be given by public providers and not captured in health plan data," he told the committee. "We are trying to develop the capability of linking state immunization registry exposure data to health plans membership data, which can provide us outcome data."

Participating health plans, which include Aetna, CIGNA, Humana, HealthCore, and WellPoint plans in California, New York, and Colorado, and Blue Cross Blue Shield in Michigan, will provide data on some 25 million people.

The state registries that are participating in PRISM are from Arizona, Florida, Georgia, Michigan, Minnesota, New York (as well as New York City), Pennsylvania, and Wisconsin, and these will provide data on an additional 14 million people.

The exchange of data between health plans and registries is a new experience for everyone, Dr. Platt noted.

To ensure that data sharing protects patient confidentiality, PRISM has been classified as a public health practice, not as research, "so there is no [internal review board] approval that is governing this," he said.

The various health plans and states are encouraged to use the Health Insurance Portability and Accountability

Act public health exemption for exchange of protected health information. All person-level data will remain at the health plans after transformation to a standard format.

"This is a very robust and reassuring way to extract the information that is needed to support public health purposes while ensuring the privacy of the health information," he said.

PRISM started in September, and the first data should become available within 2 weeks, around early December, Dr. Pratt said.

"PRISM is enhancing vaccine safety by framing safety surveillance as a public health activity, by creating public-private collaborations for public health, by implementing methods for rapid analysis of data, and by developing methods for responding to findings," he concluded.

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