



Safety of Influenza A (H1N1) 2009 Monovalent Vaccines --- United States, October 1-- November 24, 2009

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The Food and Drug Administration (FDA) licensed the first 2009 influenza A (H1N1) monovalent vaccines ("H1N1 vaccines") on September 15, 2009 (1). The H1N1 vaccines are available as a live, attenuated monovalent vaccine (LAMV) for intranasal administration and as monovalent, inactivated, split-virus or subunit vaccines for injection (MIV). The licensure and manufacturing processes for the monovalent H1N1 vaccines were the same as those used for seasonal trivalent inactivated (TIV) or trivalent live, attenuated influenza vaccine (LAIV); none of these vaccines contains an adjuvant (1). Vaccine safety monitoring is an important component of all vaccination programs. To assess the safety profile of H1N1 vaccines in the United States, CDC reviewed vaccine safety results for the H1N1 vaccines from 3,783 reports received through the U.S. Vaccine Adverse Event Reporting System (VAERS) and electronic data from 438,376 persons vaccinated in managed-care organizations in the Vaccine Safety Datalink (VSD), a large, population-based database with administrative and diagnostic data, in the first 2 months of reporting (as of November 24). VAERS data indicated 82 adverse event reports per 1 million H1N1 vaccine doses distributed, compared with 47 reports per 1 million seasonal influenza vaccine doses distributed. However, no substantial differences between H1N1 and seasonal influenza vaccines were noted in the proportion or types of serious adverse events reported. No increase in any adverse events under surveillance has been seen in VSD data. Many agencies are using multiple systems to monitor H1N1 vaccine safety (2). Health-care providers and the public are encouraged to report adverse health events that occur after vaccination.

Reports to VAERS

Health-care providers and manufacturers are required to report to VAERS certain adverse events in vaccinees brought to their attention after vaccination with licensed U.S. vaccines;* however, health-care providers and members of the public also may report other adverse events voluntarily. VAERS enables early detection of potential new, rare, or unusual patterns of adverse events, which then can be investigated using other methods and systems to determine whether an actual association with vaccination exists (3). With the initiation of the federal H1N1 vaccination program, VAERS was enhanced by providing VAERS contact information on influenza vaccination record cards, advertising in medical journals, utilizing state vaccine safety coordinators, and increasing the

number of staff members who code reports and obtain and review medical records; these changes were made to encourage VAERS reporting and to increase the capacity to analyze additional reports to rapidly identify any safety signals.

CDC and FDA staff members searched the VAERS database to identify all U.S. reports of adverse events after vaccination with H1N1 vaccines and 2009--10 seasonal influenza vaccines during July 1--November 24. The first doses of H1N1 LAMV became available to the public in the United States on October 5, and H1N1 MIV became available the following week. VAERS reports were coded as fatal or nonfatal serious adverse events (defined by federal regulation as those resulting in death, life-threatening illness, hospitalization, prolongation of hospitalization, persistent or significant disability, or congenital anomaly) or as nonserious,[†] and reporting rates per 1 million doses distributed as of November 20 were calculated.[§]

VAERS reports coded as serious adverse events are reviewed by medical officers and assigned to predetermined broad diagnostic categories. To verify the reported event, medical records are requested and reviewed for all serious adverse event reports and for any reports (both serious and nonserious) that describe patients with possible Guillain-Barré syndrome or anaphylaxis. Cause of death is determined as stated in medical or autopsy records. Reports to VAERS indicate only that health events occurred after vaccination; causality generally cannot be determined solely by reports to VAERS. Excluded were 62 reports with insufficient information.

Through November 24, VAERS received 3,783 reports of adverse events after receipt of H1N1 vaccine, of which 204 were categorized as serious, and 4,672 reports after receipt of seasonal influenza vaccines, of which 283 were serious. During October 5--November 20, a total of 46.2 million doses of H1N1 vaccines (11.3 million LAMV and 34.9 million MIV doses) and 98.9 million doses of seasonal influenza vaccines were distributed to U.S. states and territories. The overall VAERS adverse event reporting rates were 82 per 1 million H1N1 vaccine doses distributed and 47 per 1 million seasonal influenza vaccine doses distributed. The serious adverse event reporting rates were 4.4 and 2.9 serious adverse events per 1 million doses distributed for H1N1 vaccines and seasonal influenza vaccines, respectively. However, the percentage of serious adverse events among all adverse events reported after receipt of seasonal influenza vaccines was slightly higher (6.1%), compared with the percentage of serious adverse events after receipt of H1N1 vaccines (5.4%), and this finding was consistent for inactivated (5.8% versus 5.5%) and live attenuated (7.3% versus 4.7%) vaccines ([Table 1](#)).

VAERS received 13 reports of deaths occurring after receipt of H1N1 vaccine; three deaths occurred after receipt of LAMV and 10 after receipt of MIV ([Table 2](#)). In nine of these deaths, significant underlying illness (including illness that might be indication for vaccination) was present; one death resulted from a motor vehicle crash, and the remaining three deaths await review of final autopsy results or death certificates by CDC.

As of November 24, VAERS had received 10 reports of Guillain-Barré syndrome, and two additional reports of possible Guillain-Barré syndrome were identified by medical officers reviewing other reports to VAERS describing neurologic events. After chart review, four of these 12 reports (all after receipt of MIV) met Brighton Collaboration criteria[¶] for Guillain-Barré syndrome, four did not meet the criteria, and four are under review. VAERS also received 11 reports of anaphylaxis, and an additional eight reports of possible anaphylaxis were identified by medical officers reviewing reports to VAERS of serious allergic events. Of these 19 cases, 13 met Brighton Collaboration criteria, five had an anaphylaxis diagnosis on medical record review, and one has not been confirmed. Three of the Guillain-Barré syndrome cases and 15 of the anaphylaxis cases were coded as serious adverse events, in accordance with federal regulation.

The remaining 173 nonfatal serious adverse events after vaccination with H1N1 vaccines are under chart review. These reports fall into the following diagnostic categories: neurologic or muscular condition other than Guillain-Barré syndrome (49 [28%]); pneumonia or influenza-like illness (27 [16%]); other noninfectious conditions, including multiple medical symptoms (19 [11%]); respiratory or ear, nose, and throat condition (17 [10%]); allergic conditions other than anaphylaxis (16 [9%]); pregnancy complications** (15 [9%]); other infectious symptoms (10 [6%]); gastrointestinal (eight [5%]); cardiovascular (six [3%]); and psychiatric (six [3%]). Each category includes a variety of diagnoses; no patterns were identified.

VSD Data

VSD is a collaboration between CDC and eight managed-care organizations with a total of 9.5 million members, which utilizes administrative data and electronic medical records to collect information on vaccinations and health-care encounters to monitor vaccine safety. VSD is monitoring H1N1 vaccine safety using historical and other appropriate comparison groups, with weekly data analyses (4). As of November 21, 438,376 doses of H1N1 vaccines (323,345 MIV and 115,031 LAMV) had been administered to patients under VSD surveillance. During October 1--November 21, no cases of Guillain-Barré syndrome and one case of anaphylaxis were observed among vaccinated persons in VSD. In addition, VSD has detected no increase in rates for other monitored conditions: demyelinating disease, peripheral nervous system disease, seizure, encephalomyelitis, Bell's palsy, other cranial nerve disorders, ataxia, allergic reactions, and myocarditis. VSD will continue H1N1 vaccine safety monitoring throughout the vaccination campaign.

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Editorial Note:

Seasonal influenza vaccines consistently have had excellent safety profiles, as documented in recent multiyear studies (5). However, in 1976, a vaccine against a swine-origin influenza virus was associated with a small, but statistically significant, increased risk for Guillain-Barré syndrome among adult vaccinees in the 8 weeks after vaccination (attributable risk: 1 per 100,000 vaccinees). The reasons for this association remain unknown. Vaccine production has changed since 1976, with increased use of vaccines which are treated with solvents to produce split-virus vaccines, or with detergents to produce subunit vaccines, resulting in fewer adverse reactions. However, the historical association with the swine-origin influenza virus of 1976, high public expectations for the H1N1 vaccine program, and the federal commitment to ensure vaccine safety all have contributed to efforts to enhance vaccine safety monitoring systems for H1N1 vaccines.

In clinical trials of the four H1N1 vaccine products licensed in the United States in September 2009, most adverse events were mild and similar to those described after receipt of seasonal influenza vaccines (Sanofi Pasteur, Inc.; Novartis Vaccines and Diagnostics, Inc; CSL Limited; and MedImmune LLC; unpublished data, 2009) (5,6). However, these clinical trials were limited in size and not designed to detect rare adverse events after vaccination. Moreover, they generally included only healthy volunteers. Additional vaccine trials of the H1N1 vaccines are being conducted by the National Institute of Allergy and Infectious Diseases (NIAID) in approximately 4,000 persons aged 6 months to >65 years, including approximately 200 pregnant women.^{††} To date, no serious adverse

events associated with receipt of these vaccines have been identified by independent safety monitoring committees (C. Heilman, personal communication, NIAID, 2009).

Data from VAERS indicated that the overall reporting rate after H1N1 vaccination was higher than the rate after seasonal influenza vaccination. Although these data might represent an actual difference in the safety of the vaccines, the difference might have resulted from efforts to enhance reporting to VAERS and heightened public awareness of the H1N1 vaccines. VSD has the capability to test and strengthen hypotheses generated by VAERS reports. To date, preliminary VSD data indicate no increase above background rates for monitored health events among recipients of H1N1 vaccines. VSD, because of its ability to follow populations of vaccinated and unvaccinated persons over time, can detect associations between health events and vaccination. This and other systems will continue to monitor adverse events after H1N1 and seasonal influenza vaccination and can help determine whether adverse events after vaccination are causally related to the vaccines ([Table 3](#)).

The findings in this report are subject to at least three limitations. First, as a voluntary reporting system VAERS is subject to underreporting, and the use of the number of vaccine doses distributed as the denominator for calculating adverse event reporting rates also contributes to lower rates than would have been calculated using the number of doses administered. However, distribution data are the best available for rapid calculations and have been used previously for vaccine safety assessments (3,5). Second, VAERS reports provide only preliminary diagnoses; these diagnoses are validated later with medical record reviews. Even when diagnoses are validated, VAERS reports do not enable conclusions to be drawn regarding associations between vaccination and the adverse events reported. In addition, medical conditions that might develop months after vaccination could not be captured in this VAERS analysis, which included only 2 months of postvaccination experience. Finally, for the VSD analysis, the number of H1N1 vaccine doses administered within the managed-care organizations had not yet reached an adequate level to detect small increases in risk for rare diseases. For example, 400,000 doses administered would enable detection of an increased risk for Guillain-Barré syndrome as large as the seven-fold increase observed after the 1976 vaccinations; however, 800,000 doses would be needed to detect only a two-fold increase.

The 13 deaths reported to VAERS reflect a range of underlying conditions, some of which cannot be reasonably attributed to vaccination. No patterns in age, sex, or type of underlying medical condition were observed that might lead investigators to suspect a causal link with vaccination. Regarding Guillain-Barré syndrome cases reported after H1N1 vaccination, the currently reported number of cases appears substantially smaller than the number expected from a population of 30--40 million persons, but underreporting to VAERS and differences in vaccinated and background populations make the comparison complex. Guillain-Barré syndrome monitoring and evaluation are continuing using VAERS, VSD, and enhanced Guillain-Barré syndrome surveillance systems ([Table 3](#)). In 15 years of VAERS experience with TIV, 28% of severe adverse event reports were classified as neurologic or muscular conditions, 11% as respiratory, and 6% as gastrointestinal (5), percentages comparable with those observed (28%, 10%, and 5%) in these initial reports after H1N1 vaccination.

A comprehensive vaccine safety monitoring and response program is necessary to detect possible increases in adverse health events and formulate hypotheses for further investigation and testing. VAERS data can detect safety signals (i.e., new, unexpected or rare adverse events) but generally cannot be used to infer causality (3). Once a large enough number of vaccine doses have been administered in its member managed care organizations, VSD can better identify associations between vaccination and health events (4). Recently, new vaccine safety monitoring systems have been developed to augment existing surveillance systems by focusing on specific health events (e.g.,

Guillain-Barré syndrome or pregnancy outcomes) and to estimate background rates for selected medical conditions, conduct case-control studies, and assess causality (Table 3). These additional systems will enhance the ability to determine whether the difference in the VAERS reporting rate between H1N1 and seasonal influenza vaccines can be attributed to reporting bias or safety differences. To synthesize and evaluate data on H1N1 vaccine safety, a nongovernment working group has been established by the National Vaccine Advisory Committee^{§§} with members representing other federal advisory committees as well as experts in internal medicine, pediatrics, immunology, and vaccine safety. The group will meet every 2 weeks and will provide reports to the public through the National Vaccine Advisory Committee after considering data from the many available systems.

References

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* Food and Drug Administration. 21 CFR Part 600.80. Postmarketing reporting of adverse experiences. *Federal Register* 1997;62:52252--3. National Childhood Vaccine Injury Act of 1986 (42 USC 300aa-25).

† Nonserious events are defined as all others not categorized as serious adverse events.

§ Because not all distributed doses of vaccine are administered, the reporting rate per million doses distributed will underestimate the true reporting rate; however, use of this standard denominator enables comparisons with rates per million doses distributed for other vaccines. National data on numbers of doses administered are not available, and survey-based coverage estimates are available only with a time delay.

¶ Additional information available at <http://www.brightoncollaboration.org/internet/en/index.html>. Accessed November 27, 2009.

** Stillbirth, spontaneous abortion, or preterm delivery.

†† Additional information available at <http://clinicaltrials.gov/ct2/search>. Accessed November 27, 2009.

§§ Additional information available at <http://www.hhs.gov/nvpo/nvac>. Accessed November 27, 2009.

What is already known on this topic?

Vaccine safety monitoring is an important component of all vaccination programs and can address concerns that the current H1N1 vaccines might increase the risk for neurologic complications such as occurred with Guillain-Barré syndrome and the 1976 swine influenza vaccine.

What is added by this report?

CDC review of reports from the U.S. Vaccine Adverse Event Reporting System showed no concerning safety signals (i.e., new, unexpected, or rare adverse events), and analysis of data from the Vaccine Safety DataLink found no increased occurrence of monitored conditions after H1N1 vaccination.

What are the implications for public health practice?

CDC and other agencies will use additional systems and continue to monitor H1N1 vaccine safety closely; health-care providers should continue to report adverse events after H1N1 and seasonal influenza vaccinations.

TABLE 1. Adverse events reported after receipt of influenza A (H1N1) 2009 monovalent vaccines and seasonal influenza vaccines --- Vaccine Adverse Event Reporting System (VAERS), United States, July 1-- November 24, 2009

Influenza vaccine received	All reports of adverse events*	Serious adverse events [†]						Nonserious events [†]	
		Total		Fatal		Nonfatal			
		No.	(%)	No.	(%)	No.	(%)	No.	(%)
H1N1 total	3,783	204 (5.4)	13 (0.3)	191 (5.0)	3,579	(94.6)			
Live, attenuated monovalent vaccine	1,115	52 (4.7)	3 (0.3)	49 (4.4)	1,063	(95.3)			

Monovalent inactivated, split-virus or subunit	2,439	135 (5.5)	9 (0.4)	126 (5.2)	2,304 (94.5)
Unknown	229	17 (7.4)	1 (0.4)	16 (7.0)	212 (92.6)
Seasonal total	4,672	283 (6.1)	16 (0.3)	267 (5.7)	4,389 (93.9)
Live, attenuated influenza vaccine	480	35 (7.3)	0 ---	35 (7.3)	445 (92.7)
Trivalent inactivated	4,028	232 (5.8)	15 (0.4)	217 (5.4)	3,796 (94.2)
Unknown	164	16 (9.8)	1 (0.6)	15 (9.1)	148 (90.2)

* An adverse event reported to VAERS might occur by chance after vaccination or might be related causally to vaccine; VAERS generally does not determine whether a vaccine caused an adverse event. Excluding 62 reported with insufficient information, of which two were serious adverse events: one allergic and one local reaction (i.e., cellulitis at the injection site).

† Serious adverse events are defined as those resulting in death, life-threatening illness, hospitalization, prolongation of hospitalization, persistent or significant disability, or congenital anomaly. All other events are categorized as nonserious. Food and Drug Administration. 21 CFR Part 600.80. Postmarketing reporting of adverse experiences. Federal Register 1997;62:52252--3.

TABLE 2. Patient age, sex, and clinical characteristics regarding the 13 reported deaths after receipt of influenza A (H1N1) 2009 monovalent vaccines --- Vaccine Adverse Event Reporting System, United States, 2009*

Age (yrs)	Sex	H1N1 vaccine type	Vaccination to onset (days)	Medical history	Preliminary diagnosis/Autopsy results
1	Male	MIV [†]	1	Febrile seizures (one after measles, mumps, rubella vaccination)	Sudden death, no evidence of trauma

2	Female	MIV	0	Encephalopathy, central apnea, traumatic brain damage, seizures	Sudden cardiopulmonary arrest
9	Female	LAMV [§]	6	Trisomy 21, leukemia (in remission), cardiac disease (neutropenia on vaccination day)	Pneumococcal pneumonia/H1N1 influenza
18	Male	LAMV	0	No significant history, dental care for gingivitis 2 weeks before H1N1 vaccination; enlarged heart on chest radiograph	Massive aspiration/ Sudden cardiopulmonary arrest
19	Female	MIV	9	Rett syndrome, severe muscle wasting/physical disability	Bilateral pneumonia, respiratory failure
35	Female	LAMV	3	Hereditary spherocytosis, splenectomy	Pneumococcal sepsis
38	Male	MIV	19	Immunocompromised	Respiratory failure/Under review
46	Female	MIV	2	Hypertension, hyperlipidemia, pulmonary embolism, deep vein thrombosis	Pulmonary embolus/Negative for H1N1 in lung tissue
49	Female	MIV	3	Type 2 diabetes, stroke, chronic obstructive pulmonary disease, emphysema, substance abuse	Suspected cardiovascular event
53	Female	MIV	5	End-stage renal disease and atrial fibrillation	Under review
56	Female	MIV	0	Driver involved in motor vehicle crash leaving clinic after H1N1 vaccination	Trauma
61	Male	MIV	13	Hypertension, diabetes, peripheral vascular disease, end stage renal disease	Cardiac/Respiratory arrest, gram- negative sepsis

77 Male MIV 2 Lung cancer atrial fibrillation, recurrent deep venous thrombosis hypertension, hyperlipidemia Suspected myocardial infarction

* As of November 24, 2009.

† Monovalent inactivated, split-virus or subunit vaccines.

§ Live, attenuated monovalent vaccine.

TABLE 3. Surveillance systems monitoring the safety of influenza A (H1N1) 2009 monovalent vaccines --- United States, 2009

System	Federal agency	Description	Approximate U.S. population monitored
Vaccine Adverse Event Reporting System (VAERS)	CDC, Food and Drug Administration (FDA)	Health-care providers and manufacturers are required to report to VAERS certain adverse events in vaccinees; health-care providers and members of the public also may report other adverse events voluntarily. VAERS enables early detection of new, rare, or unusual patterns of adverse events, which can then be investigated using other methods and systems. Enhancements to VAERS include providing information on influenza vaccination record cards, advertising in medical journals, using state vaccine safety coordinators, and increasing report processing capacity.	Entire population
Vaccine Safety Datalink (VSD)	CDC	Uses administrative data and electronic medical records to collect information on vaccinations and health-care encounters to monitor vaccine safety. VSD is monitoring H1N1 vaccine safety using historical and other appropriate comparison groups, with weekly data analyses.	9.5 million
Population-based active	CDC	CDC and Emerging Infections Program sites actively identify Guillain-Barré syndrome	45 million

surveillance for Guillain-Barré syndrome		cases, using a network of neurologists and collaboration with the American Academy of Neurology.	
Real-Time Immunization Monitoring System	CDC	Allows vaccinees to register online at the time of vaccination; solicits reports of postvaccination adverse events with e-mails on the day of vaccination and 7 days and 42 days after vaccination.	Entire population
Post-Licensure Rapid Immunization Safety Monitoring	National Vaccine Program Office, CDC, FDA	Active surveillance using electronic billing, diagnostic, and vaccination data from state vaccine registries and large health plans in several states..	30 million (17 million with registry-enhanced data)
Defense Medical Surveillance System	U.S. Department of Defense	An executive information, electronic medical records system containing longitudinal data on U.S. active duty military personnel	1.4 million
Veterans Affairs Adverse Drug Event Reporting System (VA ADERS)	U.S. Department of Veterans Affairs	VA health system, including veterans and employees.	1.2 million
Medicare data systems	Centers for Medicare and Medicaid Services	National Claims History File and Enrollment Database for persons enrolled in fee-for-service Medicare; can be used for retrospective and prospective vaccine safety studies, primarily among persons aged ≥ 65 years	38 million
Indian Health Service electronic health records	Indian Health Service	Can conduct enhanced VAERS surveillance and provide signal detection.	1.4 million
Vaccines and Medications in Pregnancy Surveillance System	Biomedical Advanced Research and Development Authority	A collaboration of academic and professional investigators that can monitor the relationship between receipt of influenza A (H1N1) 2009 monovalent vaccines, seasonal influenza vaccines, and antiviral medications in	Prospective cohort study (1,100).

pregnancy and subsequent maternal and fetal outcomes. Case-control surveillance (2,000)

Clinical
Immunization
Safety
Assessment
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Collaboration between CDC and six academic sites with vaccine safety expertise provides broad consultation on clinical issues that arise during safety monitoring, including review of possible Guillain-Barré syndrome and anaphylaxis reports. Entire population

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