

October 6, 2010

According to the ACIP (Advisory Committee on Immunization Practices) recommendations, everyone 6 months and older should receive the 2010-2011 influenza vaccine.<sup>4</sup> This season's trivalent influenza vaccine includes A/California/7/2009 (H1N1)-like, A/Perth/16/2009 (H3N2)-like, and B/Brisbane/60/2008-like antigens. The FDA (Food and Drug Administration) approved the use of this vaccine on July 30, 2010<sup>2</sup>.

The New Mexico Department of Health (NMDOH) encourages all individuals, especially healthcare personnel (HCP) and those at an increased risk for complications, eligible for influenza vaccine to get vaccinated as soon as vaccine is available to them.

Because NMDOH has received questions from numerous healthcare providers and Infection Preventionists, we want to address some of the myths we have heard about influenza vaccination in general and about the 2010-2011 seasonal influenza vaccine (with the H1N1 strain used for the 2009-2010 monovalent vaccine) in particular:

**MYTH:** Post-vaccination immunity or protection only lasts for 4 to 5 months.

**FACT:** Studies of healthy adults demonstrate that immunity lasts for at least a year. It is recommended that eligible recipients get vaccinated as soon as vaccine is available, every year.<sup>4</sup>

**MYTH:** There is a large risk of acquiring Guillain-Barré syndrome (GBS) following influenza vaccination.

**FACT:** GBS incidence in all people unvaccinated or vaccinated, is 1-2 per 100,000 people per year. The frequency of GBS following influenza vaccination increases only by an additional 1 case in 1 million vaccinations.<sup>4</sup> The estimated risk of GBS following vaccination with the 2009-2010 monovalent H1N1 vaccine is an additional 0.8 cases per 1 million vaccinations which is comparable to the increased risk of GBS following vaccination with seasonal vaccine (1 case per 1 million vaccinations).<sup>1</sup> One study's results proves that the estimated frequency of GBS following influenza illness is 4-7 times higher than that following influenza vaccination.<sup>4</sup> These data suggest that one is more likely to develop GBS following influenza illness than following an influenza vaccination.

**MYTH:** This season's influenza vaccine is more dangerous than past seasonal vaccine because it includes a 2009 H1N1-like serotype.

**FACT:** 2010-2011 influenza vaccine has undergone the standard, strict FDA approval process.<sup>2</sup> The H1N1 serotype included in this season's vaccine has not been associated with more serious adverse events than previous seasonal influenza vaccine (which also contained other serotypes of H1N1 viral components).

**MYTH:** Influenza vaccine causes influenza disease.

**FACT:** The inactivated vaccine injection is made with noninfectious killed virus and cannot cause influenza illness. Low-grade fever or muscle aches are common side effects following the inactivated influenza

vaccination and are associated with the body's immune response to vaccination. The live-attenuated nasal spray vaccine is made with weakened influenza viruses that don't normally cause the flu. Common side effects associated with the live-attenuated vaccine are cough, sore throat, runny nose, and headache. These side effects are usually less severe than symptoms of ILI (influenza-like illness).<sup>3</sup>

**MYTH:** The 2010-2011 influenza vaccine injection hurts more than past seasonal vaccine shots.

**FACT:** Soreness, redness, or swelling at the injection site are common side effects of any injection. This season's influenza vaccine is made like previous seasons and should not be any more uncomfortable.

To summarize the evidence gathered from multiple studies on the influenza vaccinated and unvaccinated populations, several points are worthy of emphasis:

- Each year, influenza vaccine undergoes extensive safety and effectiveness studies prior to licensure, as required by the FDA. These studies have shown that the safety of the monovalent 2009-2010 H1N1 vaccine is the same as seasonal influenza vaccine. This season's H1N1-like antigen is the same serotype as the monovalent 2009-2010 H1N1 vaccine and has been approved by the FDA for use this season following rigorous testing, just as in previous seasons.<sup>2</sup>
- The H1N1 strain has begun to circulate in the U.S. and it is anticipated to circulate further in the population. Post-market studies of adverse events following monovalent 2009-2010 H1N1 vaccination reported to VAERS (Vaccine Adverse Event Reporting System) from October 1, 2009 to January 31<sup>st</sup>, 2010 demonstrated a safety profile consistent with seasonal influenza vaccines.
- There were fewer serious adverse events, including GBS, reported following the monovalent 2009-2010 H1N1 vaccine compared to the 2009-2010 seasonal vaccine (7.2 vs. 8.3%).<sup>5</sup> Preliminary results from a CDC EIP (Centers for Disease Control and Prevention Emerging Infections Program) project demonstrated rates of GBS following monovalent 2009-2010 H1N1 vaccine similar to rates following other seasonal influenza vaccines (0.8 vs. 1 additional case per million influenza vaccinations, respectively).<sup>1</sup>

Health care providers, organizations and public health entities work hard to promote healthy decision-making by patients and the general public. Historically, influenza vaccination has shown itself to be a health-promoting behavior by reducing morbidity and mortality rates in the population. There is no cure for illness caused by the influenza virus; prevention by protection with the influenza vaccination has proven to be the best method to reduce influenza illness and its complications<sup>4</sup>.

We appreciate your work in promoting and encouraging patients to receive influenza vaccination. We hope we have provided you with useful information to share with them.

1. Centers for Disease Control and Prevention (CDC). Preliminary results: Surveillance for Guillain-Barré syndrome after receipt of influenza A (H1N1) 2009 monovalent vaccine — United States, 2009–2010. *MMWR Morb Mortal Wkly Rep* 2010 June 2;59(21).
2. “2010-2011 Influenza Season Vaccine Questions and Answers”. U.S. Food and Drug Administration. Accessed 9/28/2010. <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm220649.htm>
3. “Key facts about seasonal flu vaccine”. Centers for Disease Control and Prevention (CDC). Accessed 9/28/2010. <http://www.cdc.gov/flu/protect/keyfacts.htm>
4. Fiore, AE, et. al. Prevention and control of influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. *MMWR Recomm Rep* 2010 Jul 29;59.
5. Vellozzi C, et al. Adverse events following influenza A (H1N1) 2009 monovalent vaccines reported to the Vaccine Adverse Event Reporting System, United States, October 1, 2009-January 31, 2010. In press article. *Vaccine* (2010)

