



## 2009 H1N1 Flu Vaccine Safety: Frequently Asked Questions

### **Q: Are vaccines safe?**

**A:** Vaccines are considered to be one of Public Health's greatest accomplishments. Vaccines protect people from fatal diseases, increase life expectancy, and spare millions from pain and suffering. But no vaccine is 100 percent safe. Almost all vaccines can cause pain, redness or tenderness at the site of injection. And some vaccines cause more severe side effects, although that happens rarely.

Few things in life are 100% safe. For example, every year in the United States, 350 people are killed in bath- or shower-related accidents, 200 people are killed when food lodges in their windpipe, and 100 people are struck and killed by lightning. However, few of us consider eating solid food, taking a bath, or walking outside on a rainy day as unsafe activities. We just figure that the benefits of the activity clearly outweigh the risks. The same is true of vaccines. Severe side effects happen rarely, and the great majority of people benefit by protection against disease.

### **Q. Who licenses and recommends vaccines?**

**A:** Vaccines must be licensed by the U.S. Food and Drug Administration (FDA) before they can be used in the United States. Before the FDA approves a license, vaccines are tested extensively to ensure they are safe.

The recommendation process begins only after a vaccine is approved by the FDA. Doctors follow the recommendations of experts such as the Advisory Committee on Immunization Practices (ACIP), which is part of the Centers for Disease Control and Prevention (CDC), the Committee on Infectious Diseases of the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).

### **Q. Is it possible to get the flu from a flu vaccination?**

**A:** The flu shot does not contain any of the live virus so it is impossible to get influenza from the vaccine. Side effects may occur in some people, such as mild soreness, redness or swelling at the injection site, headache, or a low-grade fever.

### **Q: Is the 2009 H1N1 influenza vaccine experimental?**

**A:** No. H1N1 influenza vaccine will be available in an inactivated, injectable formulation and a live weakened, nasal-spray formulation. Neither is an experimental vaccine. The 2009 H1N1 influenza vaccines are made employing the same methods and facilities used annually to produce yearly seasonal influenza vaccine.

### **Q. Is there a risk of Guillain-Barre Syndrome from the H1N1 flu vaccine, as may have happened in the 1976 Swine Flu outbreak?**

**A:** In 1976, a swine flu vaccine was associated with Guillain-Barre Syndrome (GBS), a rare disorder in which a person's immune system damages the nerve cells, causing muscle weakness and sometimes paralysis. The risk was very small (about 1 additional case per 100,000 people who received the vaccine.) Vaccine production techniques have changed since then. Today, vaccines are highly purified to eliminate any potential

contaminants. In addition, scientists use only selected viral proteins in the shots, not the entire virus, as they did in the 1970s. Scientists expect the 2009 H1N1 vaccine to have a safety profile similar to seasonal flu vaccines, which have very good safety track records.

**Q. Does the 2009 H1N1 flu vaccine contain thimerosal? Is thimerosal linked to autism?**

**A:** The 2009 H1N1 influenza vaccine that FDA is licensing will be manufactured in several formulations. Some will come in multi-dose vials and will contain thimerosal. Thimerosal, a mercury-based preservative, has been used for decades in multi-dose vials of some vaccines to prevent the growth of bacteria and fungi contaminants. Due to public concern that thimerosal might be linked to rising autism rates, thimerosal was removed from most vaccines for children and pregnant women in 2001. This was a precautionary measure only; valid scientific studies have shown there is no link between thimerosal and autism. In fact, autism rates have actually increased since thimerosal was removed from childhood vaccines. The American Academy of Pediatrics (AAP), the American Medical Association (AMA), the CDC, and the Institute of Medicine (IOM) agree that science does not support a link between thimerosal in vaccines and autism. Anyone still concerned about thimerosal can request one of the thimerosal-free flu vaccines: the nasal vaccine or a single-dose preloaded syringe.

**Q. What are adjuvants? Are there health risks associated with adjuvants?**

**A.** Adjuvants are substances added to vaccines to improve the immune response. Adjuvants often allow for lesser quantities of the vaccine and fewer doses. Aluminum salts such as aluminum hydroxide, aluminum phosphate and aluminum potassium sulfate are adjuvants that have been used to improve the immune system's response to vaccines for more than 70 years. The amount of aluminum added to a vaccine is very small, much smaller than the amount required to cause harm. For example, the average recommended dose of antacids has about 1,000 times more aluminum than a vaccine does.

Some of the pandemic H1N1 flu vaccines currently being tested contain adjuvants. The pandemic H1N1 vaccine that will be used in the U.S. will not contain adjuvants.

**Q. How will the 2009 H1N1 influenza vaccines be monitored for safety?**

**A.** The CDC and FDA closely monitor the safety of seasonal influenza and other vaccines licensed for use in the U.S. in cooperation with state and local health departments, healthcare providers and other partners. Two of the primary systems that are used to monitor the safety of vaccines after they are in widespread use are: the Vaccine Adverse Event Reporting System (VAERS), and the Vaccine Safety Datalink (VSD) Project. More information about these systems is available at: <http://vaers.hhs.gov> and <http://www.cdc.gov/vaccinesafety/vsd/>.