

Questions & Answers on Guillain-Barré Syndrome (GBS)

We've received a number of questions about the 1976 vaccine that was reported to have led to an increase in Guillain-Barré Syndrome (GBS). The following information is taken from the CDC Web site and contains the most accurate information to date.

What is Guillain-Barré syndrome (GBS)?

Guillain-Barré syndrome (GBS) is a rare disorder in which a person's own immune system damages the nerve cells, causing muscle weakness and sometimes paralysis. GBS can cause symptoms that last for a few weeks or several months. Most people recover fully from GBS, but some people have permanent nerve damage. In rare cases, people have died of GBS, usually from difficulty with breathing. In the United States, for example, an estimated 3,000 to 6,000 people develop GBS each year on average, whether or not they received a vaccination. **This is about one to two cases of GBS per 100,000 people.**

What causes GBS?

Scientists do not fully understand what causes GBS, but it is believed that stimulation of the body's immune system may play a role in its development. Here's what scientists know for sure:

- About two-thirds of people who develop GBS symptoms do so several days or weeks after they have been sick with a diarrheal or respiratory illness.
- Infection with the bacterium campylobacter jejuni is one of the most common risk factors for GBS.
- People can also develop GBS after having the flu or other infections (such as cytomegalovirus and Epstein Barr virus).
- On very rare occasions, they may develop GBS in the days or weeks following receiving a vaccination.

Who is at risk for developing GBS?

Anyone can develop GBS, but it is more common among adults than children. The incidence of GBS increases with age, and people over age 50 are at greatest risk for developing GBS.

Do vaccines cause GBS?

It is not fully understood why some people develop GBS, but it is believed that the nerve cells are damaged by a person's own immune system. Many types of infections, and in very rare cases vaccines, may activate the immune system to cause damage to the nerve cells.

How common is GBS, and how common is it after people are vaccinated for seasonal influenza?

GBS is rare. Each year, about 3,000 to 6,000 people in the United States develop GBS whether or not they received a vaccination – that's one to two people out of every 100,000 people. This is referred to as the background rate.

In 1976, there was a small risk of GBS following influenza (swine flu) vaccination; approximately one additional case per 100,000 people who received the swine flu vaccine. That number of GBS cases was slightly higher than the background rate for GBS which was one to two per 100,000.

Since then, numerous studies have been done to evaluate if other flu vaccines were associated with GBS. In most studies, no association was found, but two studies suggested that approximately one additional person out of 1 million vaccinated people may be at risk for GBS associated with the seasonal influenza vaccine.

It is important to keep in mind that severe illness and possible death can be associated with influenza, and vaccination is the best way to prevent influenza infection and its complications.

What happened in 1976 with GBS and the swine flu vaccine?

Scientists first reported a suspected link between GBS and vaccinations in 1976, during a national campaign to vaccinate people against a swine flu virus. The investigation found that vaccine recipients had a higher risk for GBS than those who were not vaccinated (about one additional case occurred per 100,000 people vaccinated).

Given this association, and the fact that the swine flu disease was limited, the vaccination program was stopped.

Why did some people develop GBS after they received the 1976 swine flu vaccine?

The Institute of Medicine (IOM) conducted a thorough scientific review in 2003 and concluded that people who received the 1976 swine influenza vaccine had a slight increased risk for developing GBS. Scientists have multiple theories on why this increased risk may have occurred, but the exact reason for this association remains unknown.

Do you expect that the 2009 H1N1 vaccine will be associated with GBS?

We expect the 2009 H1N1 vaccine to have a similar safety profile as seasonal flu vaccines, which have very good safety track records. The seasonal influenza vaccine has not been consistently associated with GBS. Although we do not expect GBS cases to occur after vaccination with the 2009 H1N1 vaccine, we will be closely monitoring for any cases out of an abundance of caution.

How will public health authorities investigate cases of GBS?

Ensuring the safety of vaccines is a high priority for CDC. CDC and its partners have an aggressive plan to actively monitor the 2009 H1N1 vaccine to ensure its safety. Several systems are in place to monitor vaccine safety. One of these systems is the Vaccine Adverse Events Reporting System (VAERS). CDC and FDA co-manage VAERS, which serves as an early warning system to collect voluntary reports about possible side effects that people

experience following vaccinations. CDC and FDA scientists review all VAERS reports and store the information in a computerized database that is monitored to detect new, unusual, or rare health events that could be possible side effects of vaccines.

In addition to the normal vaccine safety monitoring systems, CDC is proactively putting additional monitoring systems in place to ensure safety after licensing. Some of these systems include:

- Actively observing persons in defined geographic areas
- Collaborating with professional organizations for reports of any adverse events after vaccination
- Conducting thorough investigations when severe adverse events occur to determine whether they may have been associated with the vaccine

Through these numerous approaches, we will be able to detect any possible risk of GBS that might be associated with the 2009 H1N1 vaccine early in the vaccination campaign and take appropriate action.

How will the government determine if people who receive the 2009 H1N1 vaccine have an increased risk for GBS?

GBS cases occur every year in the general population for many different reasons. To monitor whether people who receive the 2009 H1N1 vaccine have an increased risk for GBS, U.S. public health officials will determine if the number of GBS cases reported among people who receive the 2009 H1N1 vaccine is higher than the number of cases reported in the general population. If there is an increase in the number of reported cases, public health officials will conduct intensive investigations. If any problems are detected with this 2009 H1N1 vaccine, they will be reported to health officials, healthcare providers, and the public, and health officials will take needed action to ensure the public's health and safety.

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