

## Press Release



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# Study: Guillain-Barré Syndrome Cases Low After 2009 H1N1 Vaccine

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*TORONTO* – A new study finds that reports of a neurologic disease called Guillain-Barré syndrome (GBS) have been low after 2009 H1N1 vaccination, according to a research study that will be presented as part of the late-breaking science program at the American Academy of Neurology’s 62nd Annual Meeting in Toronto, April 10 – 17, 2010. The study is one of the first national reports of the occurrence of GBS after 2009 H1N1 vaccination.

GBS is a rare disorder in which the body’s immune system attacks part of the peripheral nervous system, causing tingling and weakness of the arms and legs. While it is not fully known what causes GBS, it is known that about two-thirds of people who get GBS do so several days or weeks after they have been sick with diarrhea or a respiratory illness. Except for the swine flu vaccine used in 1976, no other influenza vaccines have been clearly linked to GBS. It was not anticipated that the 2009 H1N1 vaccine would be associated with an increased risk of GBS.

Scientists analyzed information obtained from the Centers for Disease Control and Prevention and US Food and Drug Administration Vaccine Adverse Event Reporting System (VAERS) and found that there were 35 reports of GBS following 2009 H1N1 vaccination around the country by the end of the year 2009. This amounts to 3.5 reports of GBS per 10 million people vaccinated. All cases of GBS except one were reported within six weeks of vaccination, with 23 cases reported within the first two weeks after vaccine administration. One report of death and one of disability were reported in the 33 patients who were hospitalized.

The number of GBS cases reported by the same researcher was only slightly higher after seasonal flu vaccination in 2009: 57 reports of GBS were received by VAERS, an estimated rate of 7.3 reports of GBS per 10 million vaccinations. The rate of GBS in the general population is estimated to be between one to four cases per 100,000 persons per year.

“Although preliminary, these reported cases of GBS do not appear to show an increased risk of GBS following vaccination with either the 2009 H1N1 or the seasonal flu strain and the safety record for these vaccines is excellent,” said study author Nizar Souayah, MD, with New Jersey Medical School in Newark. “CDC, FDA and neurologists around the world are continuing to closely monitor people after vaccination for this disease.”

Since VAERS receives voluntary reports of adverse events from manufacturers, providers, vaccines, and caregivers, cases of illness may be either over or underreported, and calculation of actual rates is not possible. VAERS cannot determine cause-and-effect, and an adverse event report only indicates that the event occurred sometime after vaccination. [The American Academy of Neurology](http://www.aan.com), along with the Centers

for Disease Control and Prevention reached out to neurologists in the fall of 2009, requesting that they report to VAERS any possible new cases of GBS following receipt of vaccination.

The American Academy of Neurology's Annual Meeting is the world's largest gathering of neurologists with more than 2,300 scientific research presentations on brain disorders.

The American Academy of Neurology, an association of more than 22,000 neurologists and neuroscience professionals, is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a doctor with specialized training in diagnosing, treating and managing disorders of the brain and nervous system such as Alzheimer's disease, Parkinson's disease, ALS (Lou Gehrig's disease), multiple sclerosis, stroke and migraine. For more information about the American Academy of Neurology, visit <http://www.aan.com>.

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