

## California Department of Public Health MEMORANDUM

**DATE:** January 27, 2010

**TO:** California Physicians and Local Health Departments

**FROM:** Immunization Branch and Communicable Disease Emergency Response Branch

**SUBJECT:** H1N1 Vaccine Safety

Back in 1976 an apparent increase in Guillain-Barré Syndrome (GBS) was noted among recipients of the swine flu vaccine. This has led to speculation about whether the 2009 H1N1 influenza vaccine that protects against a different "swine flu" might cause GBS. To date, data from California and nationwide surveillance systems are very reassuring about the safety of H1N1 vaccine. We hope that this information will be useful to clinicians in counseling their patients about H1N1 vaccination.

The California Department of Public Health (CDPH) has been collaborating with the Centers for Disease Control and Prevention (CDC), the California Emerging Infections Program (EIP), and the Los Angeles County Department of Public Health (LAC DPH) to detect adverse events potentially related to H1N1 vaccine. The team has been monitoring adverse events and aggressively investigating severe adverse events that have occurred after H1N1 vaccination.

In California, GBS cases are ascertained by queries to: 1) neurologists, infectious disease physicians, and intensivists; and 2) hospital information systems for patients with GBS ICD-9 codes. Cases reported to the California Encephalitis Project are also reviewed for neurological adverse events after vaccination. Other adverse events temporally associated with receipt of the H1N1 vaccine are identified via reports from local health departments, clinicians, and the federal Vaccine Adverse Events Reporting System (VAERS). Testing for alternative causes of certain severe events is being performed when specimens are available. Medical records are reviewed to obtain demographics, clinical symptoms, test results, and vaccine history.

Surveillance for adverse events is also occurring at the national level. CDC <u>recently summarized national H1N1 vaccine safety data (link)</u> based on reports submitted to VAERS. <u>Weekly updates on VAERS data are also published weekly (link)</u>.

Data from our surveillance systems (see table below) indicate that H1N1 vaccine has a safety profile similar to seasonal influenza vaccine. No increase beyond expected numbers of GBS cases or other adverse events beyond rates in unvaccinated patients has been observed. In some cases alternative non-vaccine etiologies have been identified from testing of case specimens.

## Table: California Data as of January 20, 2010: Doses of H1N1 Vaccine in Distributed in California: ~16 million doses Severe Adverse Events Reported After Vaccination Against 2009 Influenza A (H1N1)

Type of Adverse Event Total cases (Death Neurologic		Total cases (Deaths)
		0
0	Post-infectious encephalitis / myelitis	7* (0)
0	Seizures (without encephalitis)	11 (1)
0	Cranial nerve palsy	8 (0)
0	Other neurological syndrome	7* (0)
Anaphylaxis		11 (0)
Pregna	ancy-related complications	
0	Spontaneous abortion	10 (0)
0	Stillbirth	2 (0)
Other		8* (1)
Total		68 (2)

<sup>\*</sup> To date, a possible alternative etiology was identified in a total of eight cases – 2 'post-infectious encephalitis/myelitis' cases; 2 'other neurological syndrome' cases; and 4 'other' cases, including 1 death.

## We urge clinicians to:

- share this information with patients who have safety concerns about H1N1 vaccination; and
- submit case history and specimens whenever possible, particularly in patients with GBS and other neurologic conditions as well as in patients with a clinical syndrome compatible with infection (see contact information below).
- Report Guillain-Barré Syndrome cases by patient's residence:

Los Angeles County - Los Angeles County Department of Public Health,

✓ Sovirny Norng, 213-250-8654, <a href="mailto:snorng@ph.lacounty.gov">snorng@ph.lacounty.gov</a>

San Francisco, Contra Costa or Alameda Counties - California Emerging Infections Program,

✓ Celeste Prothro, 510-451-1344, <u>Cprothro@ceip.us</u>, (fax) 510-451-3210

Other counties - California Department of Public Health,

- ✓ Jacqueline Chan, 510-620-3985, gbsreport@cdph.ca.gov , (fax) 916-440-5969
- Report an adverse event following H1N1 vaccine:
  - ✓ Kathleen Harriman, 510-620-3767, Kathleen.Harriman@cpdh.ca.gov
  - ✓ Carol Glaser, 510-307-8613, Carol.Glaser@cdph.ca.gov
- **Submit laboratory specimens** for this project from a patient with GBS, other neurologic disorders or other adverse events including death:
  - ✓ Benjamin Feldman, 510-307-8608, Benjamin.Feldman@cdph.ca.gov