

# Acceptance of 2009 H1N1 Flu Vaccine Was Poor

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FROM AN ANNUAL CONFERENCE  
ON PEDIATRIC INFECTIOUS DISEASES

VAIL, COLO. — Acceptance of the pandemic 2009 H1N1 influenza vaccine by U.S. health care workers was, in a word, “terrible,” Dr. Adriana Weinberg declared.

A mere 37% of physicians and other health care workers were vaccinated against the pandemic virus, Dr. Weinberg reported at the conference sponsored by the Children’s Hospital, Denver.

Uptake of the vaccine by two notably high-risk patient groups—pregnant women, and children and adolescents aged 6 months to 17 years—was equally poor at 38% and 37%, respectively, said Dr. Weinberg, professor of medicine, pediatrics, and pathology, and medical director of the clinical virology laboratory at the University of Colorado Hospital, also in Denver. These data were



**Fear of side effects was the main reason cited by health care workers for not accepting the vaccine.**

DR. WEINBERG

provided to the National Vaccine Advisory Committee by the Centers for Disease Control and Prevention.

Among parents and other care providers for infants less than 6 months of age, vaccine acceptance was even worse at 14%.

Moreover, only 25% of adults aged 24–64 years with immunosuppression or other chronic medical conditions placing them at elevated risk for increased flu morbidity got vaccinated. That was essentially the same rate as in the overall U.S. population, including both high-priority and non-high-priority individuals.

As a result of this low uptake, many millions of soon-to-expire doses of pandemic 2009 H1N1 influenza monovalent vaccine are being destroyed.

In several studies, the main reason cited by health care workers and pregnant women for not accepting the vaccine was fear of side effects, especially Guillain-Barré syndrome, which was an issue with the 1976 swine flu vaccine. The safety concerns proved baseless this time around, as evidenced by consistently reassuring findings from three separate sources: the Vaccine Safety Datalink, the Vaccine Adverse Event Reporting System, and the Emerging Infections Program.

For example, there were no deaths and no cases of Guillain-Barré syndrome among recipients of 438,376 doses of the vaccine in managed care organizations participating in the Vaccine Safety Datalink. And during surveillance for Guillain-Barré syndrome conducted through the Emerging Infections Program, the rate of cases was 1.92/100,000 person-years among vaccine recipients,

**VITALS** **Major Finding:** Only 37% of physicians and other health care workers were vaccinated against the pandemic virus.

**Data Source:** CDC data provided to the National Vaccine Advisory Committee.

**Disclosures:** Dr. Weinberg disclosed serving as a consultant to MedImmune, Astellas, GlaxoSmithKline, and Merck.

compared with 1.21/100,000 person-years among nonrecipients. That 0.7/100,000 person-years excess of Guillain-Barré syndrome associated with the pandemic H1N1 vaccine is similar to that associated with the seasonal influenza vaccine, according to Dr. Weinberg.

One audience member said the reason lots more families in his practice didn’t get vaccinated

against H1N1 wasn’t fear of side effects; it was that he and other office-based physicians in his community didn’t get shipments of the vaccine until after the second and as it turned out, final, wave of the 2009 pandemic had passed.

Dr. Weinberg agreed that lack of timely vaccine availability caused by long delays in the cumbersome manufacturing process was a huge problem. A potential solution would be to produce influenza

People who have had chicken pox are at risk for shingles and postherpetic neuralgia (PHN) pain<sup>1,2</sup>  
This year, ~1 million Americans will develop shingles.<sup>1,2</sup>  
1 in 5 of them will go on to develop PHN pain<sup>1</sup>



## Indication

LIDODERM (lidocaine patch 5%) is indicated for relief of pain associated with post-herpetic neuralgia. Apply only to **intact skin**.

## Important Safety Information

LIDODERM is contraindicated in patients with a history of sensitivity to local anesthetics (amide type) or any product component.

Even a *used* LIDODERM patch contains a large amount of lidocaine (at least 665 mg). The potential exists for a small child or a pet to suffer serious adverse effects from chewing or ingesting a new or used LIDODERM patch, although the risk with this formulation has not been evaluated. It is important to **store and dispose of LIDODERM out of the reach of children, pets, and others**.

Excessive dosing, such as applying LIDODERM to larger areas or for longer than the recommended wearing time, could result in increased absorption of lidocaine and high blood concentrations leading to serious adverse effects.

Avoid contact of LIDODERM with the eye. If contact occurs, immediately wash the eye with water or saline and protect it until sensation returns.

Avoid the use of external heat sources as this has not been evaluated and may increase plasma lidocaine levels.

Patients with severe hepatic disease are at greater risk of developing toxic blood concentrations of lidocaine, because of their inability to metabolize lidocaine normally. LIDODERM should be used with caution in patients receiving Class I antiarrhythmic drugs (such as tocainide and mexiletine) since the toxic effects are additive and potentially synergistic. LIDODERM should also be used with caution in pregnant (including labor and delivery) or nursing mothers.

Allergic reactions, although rare, can occur.

During or immediately after LIDODERM treatment, the skin at the site of application may develop blisters, bruising, burning sensation, depigmentation, dermatitis, discoloration, edema, erythema, exfoliation, irritation, papules, petechia, pruritus, vesicles, or may be the locus of abnormal sensation. These reactions are generally mild and transient, resolving spontaneously within a few minutes to hours. Other reactions may include dizziness, headache, and nausea.

When LIDODERM is used concomitantly with local anesthetic products, the amount absorbed from all formulations must be considered.

vaccines in cell culture instead of eggs, something the Food and Drug Administration is very reluctant to allow, although one such flu vaccine was recently approved in Europe.

Another answer would be to identify common epitopes that confer cross-strain protection against all influenza strains, so a new vaccine wouldn't have to be created in advance of every flu season.

"There has been a big push on this. There are some good candidate epitopes emerging in the last year. We shall see," the virologist said.

The vaccine being manufactured for the coming 2010-2011 flu season contains antigens for a pandemic 2009 H1N1 influenza virus as well as a seasonal influenza A H3N2 Perth 2009 virus and an influenza B Brisbane 2008 virus.

The immunization schedule recommended by the CDC calls for a single dose of the vaccine for adults and children older than age 10 years.

Children aged 6 months to 9 years are to receive two doses 21 days apart unless they are in the minority who received the pandemic H1N1 monovalent vaccine

last season, in which case they are to get a single dose of the trivalent vaccine. Despite this recommendation, a recent randomized controlled trial concluded that a single dose may be sufficiently immunogenic in young children (JAMA 2010;303:37-46).

"We do anticipate circulation of the pandemic H1N1 strain in the next flu season, but I have to caution you that in the Southern Hemisphere, where influenza season is going on right now, there is very, very little pandemic H1N1. What predominates are the A H3N2 and the B Brisbane," she said. ■

**VERBATIM**

*'From a legal standpoint, any discount is a kickback of sorts—you are returning part of your fee to the patient—and many laws designed to thwart real kickbacks can apply.'*

Dr. Joseph Eastern, page 70

# For the many places patients may experience PHN pain LIDODERM® fits

Proven efficacy in 2 randomized, placebo-controlled clinical trials<sup>3-6</sup>

- In a 12-hour study, patients experienced pain relief at 30 minutes after the first dose vs observation cohort ( $P=0.0001$ ;  $N=35$ )<sup>4,a</sup>
  - Significant reduction in pain intensity vs placebo at hours 4-12 ( $P<0.001$  to  $P=0.038$ )
- In a 2-week study, 84% of patients had moderate to complete pain relief at 2 weeks vs placebo ( $P<0.001$ ;  $N=32$ )<sup>5,b,c</sup>

### Favorable safety profile<sup>3</sup>

- Nonnarcotic, nonsedating, nonscheduled
- May be used in patients who have comorbidities or are taking concomitant medications



Immediately discard used patches or remaining unused portions of cut patches in household trash in a manner that prevents accidental application or ingestion by children, pets, or others.

Before prescribing LIDODERM, please refer to the accompanying brief summary of full Prescribing Information.

<sup>a</sup> A randomized, double-blind, placebo-controlled, 4-way crossover trial (N=35) assessed safety and efficacy of LIDODERM. Patients were allodynic with a mean age of 75 years and mean PHN duration of 48 months. Pain intensity measured with horizontal 100-mm Visual Analogue Scale: 0=no pain and 100=worst pain imaginable. Measurements were recorded before patch application, at 30 minutes, and hours 1, 2, 4, 6, 9, and 12. Least-squares means were used as the best unbiased estimate of patients' mean values.

<sup>b</sup> Demonstrated over 14 days in a post hoc analysis of a randomized, enriched-enrollment, double-blind, placebo-controlled, crossover trial. Patients enrolled in the study had been using LIDODERM for ≥1 month (ie, enriched enrollment); mean age of 77.4 years and mean PHN duration of 7.3 years. Pain relief measured using 6-item verbal scale: 0 (worse), 1 (no relief), 2 (slight relief), 3 (moderate relief), 4 (a lot of relief), and 5 (complete relief). Patients exited the study if their verbal pain relief rating decreased more than 2 categories for any 2 consecutive days from baseline.

<sup>c</sup> Results of enriched-enrollment studies can't be generalized to the entire population; subjects in such studies may be able to distinguish the active drug from placebo based on nontherapeutic features of the treatments.

**References:** 1. Cluff RS, Rowbotham MC. *Neurol Clin.* 1998;16(4):813-832. 2. Weaver BA. *J Am Osteopath Assoc.* 2007;107(3 suppl 1):S2-S7. 3. Lidoderm Prescribing Information. Chadds Ford, PA: Endo Pharmaceuticals Inc; 2010. 4. Rowbotham MC et al. *Pain.* 1996;65(1):39-44. 5. Data on file, DOF-LD-02, Endo Pharmaceuticals Inc. 6. Galer BS et al. *Pain.* 1999;80(3):533-538.