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Evolving landscape of 2009 H1N1 influenza

As flu season continues, experts keep practitioners up-to-date

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During the first seven months of the 2009 H1N1 influenza (swine flu) pandemic (mid-April to mid-November), influenza activity in the United States has been at historic levels:

- 50 million have had influenza-like illness (mostly in younger adults and children),
- 200,000 have been hospitalized and
- 10,000 people have died (1,100 children and 7,500 younger adults).


Dr. Bernstein

The numbers are striking. Although there is recent evidence of decreasing activity in many parts of the country, one or more additional waves of infection are likely to occur during this influenza season. Thus, these numbers are expected to go even higher.

The H1N1 virus has not necessarily been more virulent than seasonal influenza virus, but it is spreading rapidly, affecting large numbers of susceptible individuals, especially children and young adults.

Virtually all influenza viruses identified to date continue to be 2009 H1N1 influenza. Although immunization is the best way to protect against influenza, important issues about the federal H1N1 vaccine campaign have been identified, which are being addressed. They include:

- unpredictable distribution and varied state/local vaccine supplies, especially in pediatric formulations;
- difficulty in meeting the informational needs of families and providers; and
- suboptimal collaboration between community vaccine administrators and medical homes.

Vaccine supply and recommendations

Approximately 85 million doses of the monovalent 2009 H1N1 influenza vaccine had been distributed as of Dec. 11. Supply is expected to continue to improve, and vaccine will continue to be distributed through individual state public health programs.


Dr. Bradley

Finding the proper balance between giving vaccine to as many people as possible, while targeting top priority groups, has been a conundrum. The guiding principle of current recommendations is to vaccinate as many persons as possible as quickly as possible with an emphasis on vaccinating certain target groups with an initial dose of vaccine.

There is enough flexibility in the recommendations to allow staged prioritization to meet local and state needs and to capture many of the following groups felt to be in greatest need for the monovalent 2009 H1N1 influenza vaccine:

- pregnant women,
- household contacts of infants younger than 6 months,
- all children 6 months through 4 years of age,
- children 5 through 18 years of age with chronic medical conditions that increase their risk for complications from the flu, and
- health care workers and emergency services personnel who provide direct patient care or have contact with infectious substances.

Stay informed about when and where additional vaccine doses might be available in your community. Ultimately, it is hoped that all persons 6 months through 24 years of age and all 25- through 64-year-olds with chronic medical conditions that place them at increased risk of complications from influenza can receive vaccine.

Pandemic influenza has created a public health state of emergency. Coupled with the recognized vaccine shortage, some providers have used the 2009 H1N1 influenza vaccines off-label to improve coverage, such as:

- combining two 0.25 mL doses manufactured for younger children to give as the required 0.5 mL dose for older children;
- splitting a 0.5 mL vaccine dose to create 0.25 mL doses for younger infants and toddlers;
- giving a vaccine licensed for children 4 years of age and older to those as young as 36 months of age; and
- offering the intranasal formulation to children who are not completely "healthy" (e.g., diabetics).


Dr. Bocchini

Normally, it is recommended that pediatricians follow the Food and Drug Administration indications for vaccine use. However, these unprecedented times call for special considerations. Before any off-label use, it would be best to discuss specific usage with your local pediatric infectious diseases experts and/or state health department authorities because the safety and efficacy of H1N1 vaccines used off-label have not been studied.

Seasonal influenza

Do not forget that most people and all children from 6 months through 18 years of age also need to receive the seasonal influenza vaccine. A total of 114 million doses of trivalent seasonal influenza vaccine have been manufactured.

It is too early to know if seasonal influenza viruses (i.e., seasonal H1N1, H3N2, influenza B) will circulate widely or how well the seasonal vaccine and circulating strains will match. The 2009 H1N1 influenza vaccine

is expected to provide little to no protection against the seasonal influenza viruses likely to circulate this winter, so both influenza vaccines are recommended.

In addition, the Centers for Disease Control and Prevention (CDC) has reviewed epidemiologic and serologic data from studies done in the United States and other countries. So far, receipt of seasonal influenza vaccine neither increases nor decreases the risk of getting 2009 H1N1 influenza disease.

RESOURCES

Monitor the AAP (http://aap.org/advocacy/releases/swineflu.htm) and CDC (www.cdc.gov/h1n1flu/) Web sites, as recommendations continue to evolve.

Vaccine safety

Vaccine safety monitoring is a continuous process. The monovalent 2009 H1N1 influenza vaccine has been manufactured similarly to seasonal trivalent inactivated (TIV) or trivalent live, attenuated influenza vaccine (LAIV). None of these vaccines contains an adjuvant.

Health care providers and the public are encouraged to report adverse health events that occur after vaccination. Using data from the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD), the CDC recently reviewed H1N1 vaccine safety during the first two months of reporting. No substantial differences between 2009 H1N1 influenza and seasonal influenza vaccines in the proportion or types of serious adverse events reported were found. No increase in any adverse events under surveillance has been seen in the VSD data, involving almost 440,000 vaccinated persons.

Thirteen deaths have been reported to VAERS, which reflect a range of underlying conditions. No patterns in age, sex or underlying medical condition were observed that might suggest a causal link with vaccination. The reported number of cases of Guillain-Barre syndrome after H1N1 vaccination appears substantially smaller than the number of cases expected as part of the normal background rate.

In addition, the National Vaccine Advisory Committee has established a non-government working group to synthesize and evaluate data on 2009 H1N1 influenza vaccine safety. Membership includes those representing other federal advisory committees as well as experts in internal medicine, pediatrics, immunology and vaccine safety. This safety monitoring group will meet every two weeks and regularly provide reports to the public.

Antiviral treatment

Roche Laboratories Inc. is reporting an increased supply of available oseltamivir (Tamiflu) pediatric formulations including:

- oral suspension (12 mg/mL),
- 30 mg and 45 mg "small" capsules to swallow,
- 30, 45 and 75 mg capsules that can be mixed with a sweetened liquid at home, and
- pharmacist-compounded suspension from adult 75 mg capsules (15 mg/mL).

In addition to the 75 mg capsule adult formulation of oseltamivir, Roche now expects to have an adequate supply of oral suspension and small capsules throughout the remaining 2009-'10 influenza season.

Antiviral treatment with oseltamivir (Tamiflu) or zanamivir (Relenza) is recommended for all patients with confirmed or suspected influenza virus infection who are hospitalized and/or who are at greater risk for influenza complications. Be sure families know how to recognize influenza-like illness, when to call their health care provider and which "high-risk" patients might benefit from early antiviral medication.

The majority of 2009 H1N1 influenza viruses are susceptible to the neuraminidase inhibitor antiviral medication oseltamivir. However, rare sporadic cases of oseltamivir-resistant 2009 H1N1 influenza viruses have been detected. All of the oseltamivir resistant viruses identified have been sensitive to zanamivir.

Drs. Bernstein and Bradley are members of the AAP Committee on Infectious Diseases (COID). Dr. Bocchini is chair of COID.