

MEMORANDUM

TO: State Executives
AHCA/NCAL Leadership and Members

FROM: Janice Zalen, Sr. Director of Special Programs

SUBJECT: H1N1 Update No. 20

DATE: July 28, 2009

Preparations for Massive Immunization Campaign Underway

Federal, state and local governments are gearing up for a massive novel H1N1 influenza vaccination campaign this fall. Earlier this month, the Centers for Disease Control and Prevention (CDC) issued guidance for state and local public health departments to assist them in planning for the novel H1N1 influenza vaccine campaign. The guidance provides planning scenarios for state and local governments to target high-priority populations for vaccination. The guidance may be accessed at <http://www.cdc.gov/h1n1flu/vaccination/statelocal/planning.htm>.

According to *Novel H1N1 Questions and Answers (Q&A)*, which CDC issued on July 20, every state is developing a vaccine delivery plan. It is anticipated that vaccine will be available in a combination of settings such as vaccination clinics organized by local health departments, healthcare provider offices, schools, and other private settings. This document may be accessed at http://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm.

On July 24, CDC issued *Novel H1N1 Vaccination Planning Q&A*. According to this document, H1N1 vaccine will be procured and purchased by the federal government and made available to vaccinators at no cost. HHS also plans to provide needles, syringes, sharps containers and alcohol swabs.

In answer to the question about whether states have flexibility regarding prioritization, CDC states: "State and local health departments are strongly encouraged to adhere to national guidelines on vaccine prioritization. Uniformity in prioritizing vaccine is considered a significant national interest. There may be instances where specific local needs should be taken into consideration when implementing prioritization, but deviation from national guidelines should be minimized." The Q&As are available at <http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm>.

The Advisory Committee on Immunization Practices (ACIP) convened an urgent meeting today, July 29, and based on current information on novel H1N1 Influenza A, recommended targeting the following populations for H1N1 vaccine (which will be in limited supply):

1. Pregnant women;
2. Household contacts of children under 6 months old;
3. Healthcare workers and emergency personnel;
4. Children and young adults who are between the ages of 6 months and 24 years; and
5. Non-elderly adults with conditions that make them high risk.

The elderly are not a targeted population because to a large extent, H1N1 has spared that population. They remain a priority for seasonal influenza where they are at high risk of complications.

The five target groups total about 159 million individuals and initially, it is anticipated that there will be about 120 – 160 million doses of vaccine available. Since the expectation is that protection will require 2 doses, there may be a need to prioritize within the targeted populations. On the other hand, CDC noted that not all the targeted population will opt for vaccine and there may be enough for those who want the vaccine. Although ACIP prefers that there not be prioritization, they did recommend subsets within the targeted populations. The first two categories remain the same. The third category, healthcare workers and emergency personnel, would be limited to those in direct contact with infectious individuals. The last two categories were also narrowed to a subset of each.

Vaccine Safety and Efficacy

Scientists in a network of medical research institutions are beginning clinical trials to gather critical data about influenza vaccines, including two candidate H1N1 flu vaccines. The research is under the direction of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. Initial studies will look at whether one or two doses of H1N1 vaccine are needed to induce a potentially protective immune response in healthy adult volunteers (aged 18 to 64 years old) and elderly people (aged 65 and older). If early information from those trials indicates that these vaccines are safe, similar trials in healthy children (aged 6 months to 17 years old) will begin.

A panel of outside experts will conduct a close review of the safety data from these trials to spot any safety concerns in real time. Information from these studies in healthy people will help public health officials develop recommendations for immunization schedules, including the optimal dosage and number of doses for multiple age and groups, including adults, the elderly, and children. The trials are being conducted in a compressed

timeframe in a race against the possible autumn resurgence of 2009 H1N1 flu infections that may occur at the same time as seasonal influenza virus strains begin to circulate widely in the Northern Hemisphere. For more information, the NIAID press release may be accessed at <http://www.nih.gov/news/health/jul2009/niaid-22.htm>.

N-95 Respirators

It appears that the CDC Healthcare Infection Control Practices Advisory Committee's (HCPAC) recommendation that health care workers should wear a surgical or procedure mask for the routine care of patients with confirmed or suspected influenza 2009 A (H1N1) virus infection will not be accepted by CDC anytime soon. In a CMS Survey & Certification Emergency Preparedness Stakeholder Communication Forum Teleconference today, CDC's Michael Doney stated that CDC's Infection Control Interim Guidance, which currently recommends N-95 respirators for routine care of H1N1 patients, will not be revised before about mid-October. CDC will wait for a report from the Institute of Medicine who will be convening an expert panel on the topic next month. (See AHCA's H1N1 Update No. 19 at http://www.ahcancal.org/facility_operations/clinical_practice/Pages/SwineFluUpdate19.aspx for more information on the HCPAC recommendation and the IOM panel.) In response to a question that pointed out that leaving this issue unresolved until October, makes planning particularly difficult for long term care facilities who currently do not use N95s, Dr. Doney stated that CDC would wait regardless as "there are varying interpretations of the research." In response to a follow-up question to CMS about the appropriateness of surveyor guidance on N-95s while the issue is unresolved, CMS responded that they are in discussions on that issue.