CDC Offers Vaccination Administration Guidance

BY HEIDI SPLETE

The Centers for Disease Control and Prevention offers novel influenza A(H1N1) vaccination planning guidance of interest to clinicians, as well as to state and local governments, on its Web site.

The CDC's vaccination planning Q&A page addresses issues including vaccine administration and cost.

When administering the vaccine, physicians and other health care planners should assume that two doses will be needed. This will not be confirmed "until the late summer- early fall, once clinical trials are completed," the site says. Among other points from the Q&A:

▶ **Dosage:** Physicians should assume 21-28 days between the first and second vaccinations, but at this time there will be no federal requirement to recall individuals for a second dose if necessary. The first and second doses may not be the same product, although ideally they will.

▶ **Formula:** An adjuvanted H1N1 vaccine is unlikely, but the exact formulation of the vaccine will vary by provider, and the CDC will provide more information about adjuvants, storage requirements, and mixing procedures once data from the vaccine's clinical trials are available.

▶ **Logistics:** Clinical trials are ongoing, but the CDC expects that the H1N1 vaccine may be given at the same visit as the seasonal flu vaccine.

▶ **Pneumococcal vaccine:** While there is potential for increased risk of pneumococcal disease associated with influenza, the CDC has no new recommendations for administering the pneumococcal vaccine to groups other than those for whom it is currently recommended. But this could change as summer flu epidemiologic data become available.

In response to a CDC query regarding cost, America's Health Insurance Plans (AHIP) said, "Public health planners can make the assumption that health plans will provide reimbursement for the administration of a novel (A) H1N1 vaccine to their members by private sector providers in both traditional settings e.g., doctor's offices, ambulatory clinics, health care facilities, and in nontraditional settings, where contracts with insurers have been established." AHIP is an organization representing more than 1,000 health insurance companies in the United States.

The CDC's guidance for other issues related to the cost of H1N1 vaccination includes:

▶ **The uninsured:** Private providers will be able to charge uninsured patients up to the allowable Medicare charge for their region.

▶ **Public health clinics:** Public health clinics will receive "implementation funds to support H1N1 vaccination clinics," according to the Web site. "Public health departments can bill . . . for an H1N1 vaccine administration fee, but cannot turn anyone away due to inability to pay." ■

For the CDC's Q&A on H1N1 vaccination planning, visit www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm.

Health Workers' Flu Protection Addressed

BY HEIDI SPLETE

WASHINGTON — Surgical mask or N95 respirator? The question of whether the Centers for Disease Control and Prevention should advise the use of respirators as standard protective gear by health care workers at risk for exposure to the novel influenza A(H1N1) virus was featured at a workshop sponsored by the Institute of Medicine.

The workshop served as "an open, on-the-record, information-gathering session" for the Institute of Medicine's Committee on Personal Protective Equipment [PPE] for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A, said Dr. Kenneth Shine, chair of the committee. The committee is charged with sending a draft report to the CDC with recommendations for updated guidance on H1N1-related PPE for health care workers.

Regardless of any changes in recommendations, PPE is only one layer in a health care worker's protection against the virus, said Dr. Toby L. Merlin, deputy director of the CDC's influenza coordination unit.

"We believe emphatically that PPE is one element in a hierarchy of controls," Dr. Merlin explained. Other measures to control the spread of the novel H1N1 virus currently recommended by the CDC include wearing gloves and gowns when in contact with infected persons, practicing proper hand hygiene, covering coughs and sneezes, and isolating individuals who appear ill.

"There's no such thing as a risk-free environment," said Dr. Rosemary Sokas of the Occupational Safety and Health Administration. But Dr. Sokas emphasized that employers are responsible for providing workers with the highest level of protection possible. At the workshop, the committee heard results of several studies about the use of PPE in preventing flu transmission.

'The level of PPE required of emergency health care workers does have implications on their ability to do their jobs.'

DR. ISAKOV

In one study, Dr. Raina MacIntyre of the University of New South Wales, Australia, and her colleagues conducted a randomized, controlled trial of more than 1,000 health care workers in 24 hospitals in Beijing.

The study compared infection rates in individuals who wore surgical masks, N95 respirators that were fit tested, N95 respirators that were not fit tested, and controls. The respirators—regardless of whether they were fit tested—were more effective than either surgical masks or controls.

There was no significant difference in effectiveness between the fit-tested and non-fit-tested N95 respirators. The complete study results will be presented at the upcoming Interscience Conference on Antimicrobial Agents and Chemotherapy meeting this month, Dr. MacIntyre said.

Despite such findings supporting the use of N95 respirators to mitigate the spread of the H1N1 virus, requiring their use might not go over well with clinicians in the trenches, said Dr. Alexander Isakov, an emergency medicine physician from Emory University in Atlanta. Dr. Isakov also serves as director of Emory's Section on Prehospital and Disaster Medicine, and as director of the Emory Office of Critical Event Preparedness and Response.

In an emergency setting, it is not always immediately clear what is required for each patient, Dr. Isakov said. Emergency departments that are already busy and may not be able to give infected patients adequate time if personnel are burdened with PPE requirements that may not be supported by sufficient evidence, he emphasized.

"The level of PPE required of emergency health care workers does have implications on their ability to do their jobs," Dr. Isakov said. PPE recommendations must be appropriate to the mission of the health care worker, he stressed. "Adding additional burdens on the health care provider for an extra modicum of safety that can't be measured might not actually benefit the health care worker or the patients they are trying to serve," he said.

For example, if doctors take longer to manage patients because they must don full protective gear before entering each room, it could slow down operations and cause more backlogs and crowding, he explained.

The committee also heard from representatives of workers' organizations, including the Service Employees Union and the American Federation of State, County, and Municipal Employees, who expressed support for keeping the current recommendation that health care workers use N95 respirators when managing patients with H1N1. ■

Third H1N1 Test Gets Emergency Authorization

Another diagnostic test for the 2009 H1N1 influenza virus received an Emergency Use Authorization by the Food and Drug Administration.

The Focus Diagnostics Influenza H1N1 (2009) Real-Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) diagnostic test is the third H1N1 diagnostic test to be authorized by the FDA under the Emergency Use Authorization since a public health emergency involving the virus was declared, the agency said in a written statement.

The Emergency Use Authorization allows use of unapproved medical products or unapproved uses of approved medical products following a declaration of emergency.

The Focus Diagnostics test is an unapproved device. The authorization ends once the emergency is terminated or when the FDA revokes the authorization. Focus Diagnostics will be permitted to distribute the test to laboratories certified under the U.S. Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity tests.

"This authorization will contribute to the nation's capacity for accurate testing for the 2009 H1N1 influenza virus," Dr. Daniel G. Schultz, director of the FDA's Center for Devices and Radiological Health, said in a released statement.

Focus Diagnostics is a subsidiary of Quest Diagnostics and is located in Cypress, Calif.

—Mary Jo M. Dales