Committee Weighs H1N1 Vaccination Concerns

BY DOUG BRUNK

While clinical results of some influenza A(H1NI) virus vaccine trials won't be known until late September at the earliest, planning a vaccination program for the virus is well underway.

During a 2-hour teleconference, officials from the National Vaccine Advisory Committee (NVAC) provided a wide-ranging update on activities related to novel H1N1 virus vaccine development and implementation planning.

Dr. Anne Schuchat, director of the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention, noted that there have been "disruptive clusters and outbreaks" of H1N1 influenza at summer camps in the United States with "remarkable heterogeneity," with some people disproportionately affected.

"We are continuing to see illness here in the U.S., at a lower frequency than in the spring, but a very high frequency compared to a usual summer," she said. "In the Southern hemisphere, this virus is circulating together with seasonal strains and in some cases dominating, with a mix of impact on the health sector in terms of medical capacity to keep up with it."

Robin Robinson, Ph.D., director of the Biomedical Advanced Research and Development Authority (BARDA), an agency of the Health and Human Services department, noted that the HHS has contracted with five manufacturers to develop novel H1N1 virus vaccine: Four are producing an inactivated form of the vaccine, which will be available in prefilled syringes and multidose vials, and one is producing a live attenuated form.

Clinical vaccine trials will be carried out in adults first, and then proceed to pediatric populations. Dr. Robinson estimated that about 20% of the entire clinical trial population will include children.

Results from the first clinical trials—which began in mid-July—are expected by late September or early October.

Dr. Jay C. Butler, director of the CDC's H1N1 Vaccine Task Force, said that a novel H1N1 virus vaccine program will not be the same as a program for H5N1 or severe pandemic, or seasonal flu. "The great unknown is how much will we possibly see an increase in disease in the fall if all other factors remain the same, such as severity, and antigenic characteristics of the virus," he said.

Based on current epidemiology, the H1N1 Vaccine Task Force recommended that vaccine administration planning take into account certain at-risk groups, including children and staff in day care centers and in schools serving grades K-12; pregnant women; young children; persons with household contact with children less than 6 months of age; persons with underlying medical conditions; health care workers; and, when enough vaccine is available, everyone else.

Uncertainties about a vaccine rollout persist, Dr. Butler said, including the amount of vaccine required and when it will be available; its formulation; specific recommendations for use; and demand for the vaccine.

Dr. Marie McCormick, a member of NVAC who is also a professor of maternal and child health at Harvard School of Public Health, presented draft recommendations of the H1N1 Vaccine Safety Subgroup. It calls for a federal plan to monitor novel H1N1 influenza vaccine safety, "both for proper planning purposes and to provide information to the public and stakeholders (including states) about important vaccine activities."

One key recommendation says that the need "to actively monitor vaccine recipients for vaccine adverse events is critical given that the vaccine candidates will all contain a new antigen and may be combined with adjuvants that are not part of licensed vaccines in the United States."

Another recommendation calls for "transparent and independent review of vaccine safety data as it accumulates."

The NVAC voted to adopt these recommendations, which will be passed along to National Vaccine Program Director Bruce G. Gellin, for consideration.

Megan C. Lindley of the National Center for Immunization and Respiratory Diseases presented draft recommendations related to financing the administration of novel H1N1 influenza vaccine. These include voluntary first-dollar insurance coverage by public and private plans; an increased federal match for Medicaid vaccine administration reimbursement; vaccine administration reimbursement for all Vaccines for Children–eligible children, including those on Medicaid; insurance reimbursements that cover all costs associated with vaccine administration; and federal funding that supports state vaccination infrastructure and vaccine implementation.

The NVAC voted to adopt these recommendations, with some minor editorial changes.

Dr. Anne Bailowitz, medical director of environmental health and emergency programs for the National Association of County and City Health Officials, expressed concern about the implementation of a novel H1N1 virus vaccine program in light of financial challenges faced by many local health departments in the United States. In 2008, she said, 27% of local health departments had budget cuts and 53% had layoffs. This year, she said, 44% of local departments have had budget cuts and 32% have had layoffs.

Establishing local partnerships will be key to successful implementation, she said. For example, options include tailoring partners to target populations, such as ob. gyns. and nurse midwives for pregnant women, defining roles for hospitals, and encouraging large businesses to immunize their own employees.

Volunteer H1N1 vaccination providers could also include student nurses, medical school students, dental students, veterinarians, emergency medical technicians, and pharmacy chain personnel.

"The time to start talking to potential partners is now," she advised. ■

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nant women also is seen as a way to potentially protect infants who cannot be vaccinated, via transfer of maternal antibodies to newborns.

► **Group 2: Household contacts and caregivers for infants younger than 6 months of age.** The aim is to provide a possible "cocooning effect," providing indirect protection for young infants who cannot be vaccinated but are at higher risk for influenza-related complications.

► **Group 3: Health care personnel and emergency medical personnel** (including emergency medical technicians, firefighters, and others whose jobs involve routinely providing emergency medical care in communities). These individuals are seen as a potential source of infection for vulnerable patients. In addition, increased absenteeism could reduce the health care capacity.

► **Group 4: Children and adults from 6 months through 24 years of age.** Children have the highest incidence of illness, and "explosive" outbreaks in schools have been a prominent feature of the spring 2009 epidemiology of the novel H1N1 virus. Children younger than 5 years of age are at the highest risk for hospitalization, and are sources of infection for the community and in schools. Moreover, illness in children keeps parents home from work. Young adults also have high attack rates and are seen as vectors.

► **Group 5: Adults aged 25-64 years with certain medical conditions that place them at greater risk for influenza-related complications.** These include chronic pulmonary, cardiovascular, renal, hepatic, cognitive, neuromuscular, hematologic, and metabolic disorders, as well as immunosuppression caused by medications or HIV infection. About 70% of adults hospitalized thus far with nH1N1 infections had one of these conditions.

If vaccine demand exceeds availability, subgroups of the larger group, totaling 42 million people, should receive priority. The first subgroups—pregnant women and household and caregiver contacts for infants younger than 6 months of age—remain unchanged as a priority. The next subgroups include health care and emergency personnel in direct contact with patients; children aged 6 months through 4 years of age; and children with chronic medical conditions.

When vaccine availability is sufficient at the local level to routinely vaccinate initial target populations, a decision should be made in cooperation with state and local health authorities to vaccinate healthy adults aged 25-64 years first, then individuals aged 65 years and older. The last recommendation, in contrast to seasonal influenza vaccination recommendations, reflects the fact that older individuals thus far have been at lower risk for the novel H1N1 virus.

New recommendations were needed, Dr. Fiore said, because the federal government's 2007 pandemic vaccine priority guidance had been developed for the scenario of a severe pandemic with the potential for social disruption of critical infrastructure. The ACIP's Influenza Working Group concluded that current epidemiologic and immunologic evidence, combined with updated information on vaccine supply and availability timelines, indicated a need to revise recommendations that had been made during prepandemic planning.

In drafting the document that ACIP voted on, the working group assumed the following: that the severity of illness and groups at higher risk for infection or complications will be similar to what has already been observed; that the safety profile and antigen content of novel H1N1 vaccines will be similar to that of seasonal vaccine; and that adequate supplies of licensed unadjuvanted vaccine can be produced for all by approximately February 2010 but that enough vaccines for all will not be available before the next pandemic wave, expected this fall.

The working group made the assumption that pandemic vaccine and seasonal vaccine availability will overlap and both will be recommended for many population groups, that two doses will be needed for protection, and that one dose will provide minimal or no protection. ■