

H1N1 Vaccine: One May Be Enough

BY DOUG BRUNK

A single 15-mcg dose of pandemic influenza A(H1N1) vaccine provided hemagglutination titers of 1:40 or greater in 93% of infants and children, results from a multicenter study in Australia showed.

The findings “have important public health implications given that young children are at the highest risk for hospitalization and requirement for intensive care,” wrote the researchers led by Terry Nolan, Ph.D., of the Melbourne School of Population Health at the University of Melbourne.

Between Aug. 3 and Sept. 4, 2009, the researchers randomized 346 infants and children aged 6 months to 9 years to receive a two-injection regimen of monovalent, unadjuvanted H1N1 vaccine 21 days apart in doses of either 15 mcg or 30 mcg (JAMA 2010; Jan. 6 [doi:10.1001/JAMA.2009/1911]). The vaccine was produced by CSL Ltd., of Parkville, Australia.

The researchers used hemagglutination inhibition to measure antibody titers to the H1N1 antigen at enrollment and at 21-25 days after each vaccination.

After the first dose, antibody titers of 1:40 or greater were observed in 161 of 174 (93%) infants and children in the 15-mcg group and in 168 of the 172 (98%)

infants in children in the 30-mcg group. After the second dose, all study participants in both groups demonstrated antibody titers of 1:40 or greater.

No deaths occurred during the study, but two serious adverse events were reported. The first was a 4-day episode of fluctuating fever in an 8-year-old child in the 30-mcg dose group.

The second occurred in a 1-year-old child in the 15-mcg dose group, a case of viral gastroenteritis that “was considered unrelated to vaccination.”

In an accompanying editorial, Dr. Anthony E. Fiore and Dr. Kathleen M.



One 15-mcg dose of vaccine protected children against H1N1 (above).

Neuzil said that, although the finding that one dose of the H1N1 vaccine was immunogenic in most young children “is encouraging, it is premature to assume that only 1 dose will be needed to provide adequate protection for all young children based on these data” (JAMA 2009 Dec. 21 [doi:10.1001/jama.2009.1929]).

Dr. Fiore of the National Center for Infectious Diseases at the Centers for Disease Control and Prevention, Atlanta, and Dr. Neuzil of PATH, Seattle, emphasized that the antigen content administered to infants and children in the study was 15 mcg, “the equivalent of two doses of the 7.5 microgram vaccine currently licensed in the United States for this age group.”

PATH is an international nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health.

CSL Ltd. sponsored the trial with funding from the Australian government’s Department of Health and Aging. Dr. Nolan disclosed that he has been an investigator on vaccine studies sponsored by CSL and other companies, but stated that he does not own shares in CSL. Dr. Fiore and Dr. Neuzil had no financial conflicts of interest to disclose. ■

H1N1 Vaccine Production in Full Swing

BY MICHELE G. SULLIVAN

With 100 million doses of pandemic H1N1 influenza now available, Americans have a “unique opportunity” to minimize—or even prevent—a third wave of the disease this winter.

Thus far, most vaccine has been reserved for high-priority groups that are most vulnerable to H1N1, but vaccine production is now in full swing and federal officials are urging everyone to get immunized.

“For a while, low-risk groups were told to get to the back of the line and let the high-priority folks get vaccinated,” Health and Human Services Secretary Kathleen Sebelius said during a press conference in December. “Our message now is to take advantage of the increased supply and get vaccinated as soon as you can.”

Cases of H1N1 have been tapering off in the past weeks, said Dr. Thomas R. Frieden, director of the Centers for Disease Control and Prevention, Atlanta. However, the country is just 2 months into the normal flu season, which runs from October to May, and peaks in January and February.

“The situation we have now is an ebbing second wave, but the future is uncertain,” he said. “We just don’t know how many cases we will have from now until the end of the flu season. What we need now is perseverance.”

The past may provide some insight into the future, he said. “In 1967-1968, there were large numbers of [H1N1] infections in the spring and they fell during the fall. This resulted in no vaccinations in the fall and no one realized there was still lots of flu around until there were increased deaths from pneumonia in the winter.”

Complacency is a mistake, they agreed. “H1N1 has had a substantial effect,” Dr. Frieden said. “As of mid-November, there have been 47 million cases, 213,000 hospitalizations, and 10,000 deaths. This strain has been much harder on children and young adults; the number killed through mid-November was five times more than an average flu season.”

Officials also tried to dispel some public concern that the government rushed the vaccine through development with insufficient safety testing. While it’s true that the vaccine was developed, tested, and licensed in “record time,” the steps remained methodical, science-based, and complete, said Dr. Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases, Bethesda, Md.

“The process of identification and growing of the virus, and vaccine development and production, was exactly the same [as that for seasonal flu]. It was an orderly scientific process” that resulted in a highly immunogenic vaccine safe for adults, children, pregnant women, and the elderly, as well as those with asthma and HIV infection. ■

Health Providers Carry Vaccination ‘Clout’

BY DOUG BRUNK

The way Dr. Anne Schuchat sees it, physicians and other clinicians have more influence than anybody else on a patient’s decision to be vaccinated against the pandemic influenza A(H1N1) virus.

“A recommendation from a doctor or a nurse has more clout than anything that we do in Atlanta or Washington,” Dr. Schuchat, director of the National Center for Immunization and Respiratory Diseases, Atlanta, said during a Webcast on H1N1 sponsored by the Department of Health and Human Services. “As health care providers, each of us has a responsibility to talk to our patients about the risks and benefits of vaccination, and to let them know the real risks of disease.”

The Centers for Disease Control and Prevention estimates that about 1 in 6 Americans—about 47 million people—have become ill from the virus since last spring. “We think over 200,000 people have been hospitalized, and about 10,000 have died,” Dr. Schuchat said. “A disproportionate amount of those hospitalizations and deaths have been in people under 65 years of age.”

The good news is that the prevalence of H1N1 disease continues to wane, with 14 states reporting widespread activity at present, down from 32 states that reported such activity Dec. 1.

“That’s still a lot of states, and the

virus hasn’t gone away,” Dr. Schuchat cautioned. “We know from the past that there can be an increase after the holidays—another wave of disease, for instance—but right now we’re in pretty good shape, with less disease than we had a month or so ago.”

Despite the positive turn of events, U.S. Surgeon General Regina Benjamin said, many populations aren’t seeking vaccination against H1N1, particularly school-aged children, pregnant women, and racial and ethnic minorities. “For some reason people in minority groups are not taking the vaccine as much as we would like them to,” she said. “Everyone should get vaccinated.”

Dr. Nicole Lurie, Health and Human Services assistant secretary for preparedness and response, said that while increasing numbers of her patients seem to understand there is a difference between H1N1 vaccine and seasonal influenza vaccine, “they’re not always sure they need to have both. They continue to have some questions that are typical for flu shots: Is it safe? Am I going to get sick if I get a flu shot? Do I really need to do this? My answer is, ‘I think you really need to do this.’”

Other phrases she uses to motivate patients to get vaccinated include: “If you don’t want to miss work and as a result miss a paycheck, by all means get the flu shot,” and “No one can predict who’s going to get sick enough to end up in the hospital or in an intensive care

unit, and you don’t want to be there. But we have a very strong prediction that if you get your flu shot, you won’t be there.”

Dr. Schuchat emphasized that getting vaccinated will help protect people from spreading the virus to others. “As a health care provider, the last thing I want to do is spread an infection to my patients,” she said.

The Webcast moderator asked if it’s advisable to offer H1N1 vaccine to people who had a respiratory illness during the fall but didn’t get a laboratory confirmation that it was H1N1. “We do recommend that,” Dr. Schuchat said. “We’ve told providers that they don’t need to test everyone. Many of the tests that are done are not specific. You usually have to go to a reference lab in your state to confirm that it’s H1N1 virus. So what we’re telling people is that even if you’ve had two or three respiratory illness this fall, we still recommend the vaccine.”

Dr. Lurie fielded an e-mail question from a clinician who works in a nursing home. The person asked if nursing home residents or just the staff should receive the H1N1 vaccine. “It’s terribly important for nursing home staff to get both [influenza vaccines],” Dr. Lurie said. “If nursing home residents also want to get vaccinated—particularly those who are out and about—I think it would be a great idea now that the [H1N1] vaccine is widely available.” ■