Feds Give Reasons for H1N1 Vaccine Shortage

BY ROBERT FINN

The U.S. Senate's Homeland Security and Governmental Affairs Committee held a hearing to determine why vaccine for pandemic influenza A(H1N1) virus is taking so long to reach the 159 million Americans in the designated high-risk groups.

As of Nov. 23, 34% of the vaccine needed for the initial target groups was available.

In a letter to Health and Human Services Secretary Kathleen Sebelius, Sen. Joe Lieberman (I-Conn.), who chairs the committee, together with ranking minority member Sen. Susan M. Collins (R-Maine), criticized the HHS's decision to designate nearly half the U.S. population in one of the high-risk groups.

"I share your disappointment in the initial production and the supply constraints that we have today," Dr. Anne Schuchat said in her opening statement at the hearing. Dr. Schuchat is director of the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention. "We have all been victim to the biologic processes of a slow-growing virus, and it really underscores the needs for those long-term investments in the technology and the production capacity. But production is accelerating and substantial amounts are becoming available."

The committee's letter to Secretary Sebelius pointed out that an HHS advisory committee had prepared a contingency plan for an extreme vaccine shortage. According to that plan, vaccine would have been reserved for the 42 million Americans at greatest risk. But that plan was never implemented.

Instead the federal government gave state and local governments the discretion to decide how to distribute vaccine. "People rightly do not understand why in their area they are not eligible to get vaccinated, while individuals in a similar risk category across the state or city line are told they can get the vaccine," the letter reads.

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"We have been supporting state and local decision making on the best ways to put vaccine in the path of the priority populations," Dr. Schuchat said.

"We know that states are carrying this out in a variety of ways. Thirty-four states so far have initiated school-located vaccine efforts. Virtually all of the states are providing vaccines to providers. Some are using lotteries to decide who gets the vaccine. Some have ethics boards. Some are focusing on high-risk providers that serve the highest-risk children or adults," she explained.

And Dr. Schuchat noted that if the vaccine had been reserved for only the 42 million Americans at highest risk, millions of healthy school-age children would have been left out.

She said that "reasonable experts" disagreed on whether that tighter targeting would be desirable.

"I do believe that we need a thorough evaluation of the preparedness at the state and local level," Sen. Collins said at the hearing. "It does vary enormously, because some states devote a lot of resources and some states don't. Some states are making good decisions and some states aren't. And that applies to big city health departments as well."

"We are not waiting for states or cities to fail," Dr. Schuchat replied. "We are working very actively, monitoring the ordering, understanding what's going on, offering assistance, and working on some of the missteps that we believe may be happening in some areas."

At the hearing, Dr. Nicole Lurie, who is assistant secretary for preparedness and response at HHS, detailed some of the causes for the shortage. For example, while the remnants of Hurricane Ida were still menacing the Gulf Coast, some of the manufacturers' insurance carriers insisted that vaccine deliveries be delayed.

Sen. Collins focused on two other possible explanations for the shortfall: the reliance on prefilled single-use syringes and the failure to incorporate adjuvants into the vaccine formulations. Adjuvants, which are being used in H1N1 vaccines distributed in other countries, help the immune system mount a larger response to a smaller amount of vaccine, thus stretching the supply.

Dr. Lurie said that the U.S. government contracted for a mixed supply of prefilled syringes and multi-use vials. And when it became evident that there would be a shortage, the manufacturers were instructed to focus on filling the multi-use vials. Only when they had more vaccine than they could handle on those assembly lines would they start producing prefilled syringes.

The bottom line is that the issue of vials versus syringes turned out not to have an appreciable effect on the supply, Dr. Lurie said.

The adjuvant story was somewhat more complex. Dr. Lurie said that experts reviewed the decision not to use adjuvants several times, but each time they decided against changing course.

There were two main reasons, Dr. Lurie said. First, the decision to add adjuvant would take nonadjuvanted vaccine out of the system during the shift. "And number two, as I think you know, the public's confidence in vaccines in this country is just not as robust as we want it to be. Adjuvants would be a new vaccine … and we didn't really want to rock the public's confidence with a new vaccine."

Finally, Dr. Schuchat confirmed new figures illustrating the extent of the pandemic in the United States. So far 22 million Americans have been infected with H1N1 influenza, resulting in 98,000 hospitalizations and more than 3,900 deaths.

These figures are substantially higher than those that were previously released because the CDC is no longer requiring laboratory confirmation that individual cases of influenzalike illness be confirmed as H1N1 infection before being counted. ■

Data Suggest Seasonal Flu Vaccine May Mitigate H1N1

BY HEIDI SPLETE

WASHINGTON — The 2008 seasonal flu vaccine showed an overall vaccine effectiveness of 45% against infection with the pandemic influenza A(H1N1) virus in a study of military personnel conducted between April and October 2009, according to findings presented at the annual meeting of the American Society of Tropical Medicine and Hygiene.

This rate of vaccine effectiveness means that those vaccinated have a 45% lower chance of developing an infection, Dr. Jose Sanchez of the Armed Forces Health Surveillance Center in Silver Spring, Md., said in an interview. The confidence interval for the overall 45% seasonal vaccine effectiveness rate was 33%-55%.

Surprisingly, the greatest effectiveness was seen among individuals aged 17-24 years and in those aged 40 years and older, Dr. Sanchez said. Dr. Sanchez and colleagues conducted a case-control study of flu-related medical visits by active duty members of the U.S. military, compared with a control group of military individuals who presented with acute, nonrespiratory illness.

The study included 1,205 cases of H1N1 influenza and approximately four controls for each case.

Overall, 58% of the H1N1 cases occurred in individuals younger than age 25 years. After controlling for age, gender, and previous vaccination status, the seasonal flu vaccine effectiveness was 50% among those younger than 25 years, and 55% in those older than 39 years, Dr. Sanchez said. But there was no noticeable vaccine effectiveness among individuals aged 25-29 years (-6%) and an insignificant effect among those aged 30-39 years (9%).

In this military population, the live attenuated influenza vaccine (LAIV) and the trivalent inactivated vaccine (TIV) showed vaccine effectiveness of 22% and 35%, respectively. The effects of both types were significant, although the effectiveness of the LAIV just reached significance, Dr. Sanchez noted.

This rate of vaccine effectiveness means that those who are vaccinated with the seasonal flu vaccine have a 45% lower chance of developing influenza A(H1N1).

A total of 78 of the 1,205 H1N1 patients (6.5%) required hospitalization. The seasonal flu vaccination appeared to offer more protection against severe H1N1 disease, Dr. Sanchez said. The effectiveness of the seasonal flu vaccination was 62% among hospitalized patients, compared with 42% among outpatients.

Dr. Sanchez cited four previous studies of the impact of seasonal flu vaccine on H1N1 infection. Data from two studies suggested a protective effect, while data from two others, including a study from the Centers for Disease Control and Prevention, did not. "The increasing momentum of the H1N1 pandemic underscores the need for vaccination, yet there is a wide variance in vaccine effectiveness depending on the strain-match for a particular season," Dr. Sanchez said in a statement.

The U.S. military is a highly immunized population, and the results may not be applicable to civilian populations, Dr. Sanchez said.

In addition, he suggested that a combination of natural influenza infections and prior influenza immunizations may contribute to "immunological priming" and create a cross-protective effect in active-duty military settings.

But he emphasized the importance of seasonal flu vaccination, even with the flood of attention being given to the H1N1 influenza virus. In an interview, he encouraged physicians not to forget about the seasonal flu vaccine, and to remind their patients to get vaccinated.

The military is in a unique position to monitor vaccine effectiveness in young and middle-aged adults, including groups of at-risk individuals that can be studied in randomized clinical trials, and data collection is ongoing, said Dr. Sanchez.

The results may help guide both seasonal and H1N1 vaccination in the military and Department of Defense dependents, he added.

Dr. Sanchez had no financial conflicts to disclose. ■