

Volunteers can fight H1N1 pandemic

Triangle recruits will test flu vaccine

By SARAH AVERY
STAFF WRITER

About 200 people in the Triangle will be given a shot to advance world health as test subjects for vaccines against the newly declared flu pandemic.

Wake Research Associates, a Raleigh company that has previously enlisted area volunteers to try vaccines for botulism, small pox, avian flu, anthrax, herpes and regular seasonal flu, has been selected by two pharmaceutical manufacturers to test their H1N1 shots.

Volunteers are currently being recruited.

"It's such an important proj-

ect for the country and worldwide," Dr. Ella Grach, medical director for Wake Research Associates.

Each manufacturer may want as many as 100 people at the Wake Research site to be inoculated with their drugs, both of which are made by a new process that health officials hope could speed delivery time.

The vaccine manufacturers have been working with world health officials to produce a shot that protects against the new H1N1 flu strain, which erupted in Mexico this winter and has now infected nearly 29,000 people worldwide, in-

TO VOLUNTEER

For more information about volunteering to test one of the H1N1 flu vaccines, call Wake Research Associates at 781-2514 or go to www.wakeresearch.com.

cluding more than 13,000 in the United States and 83 in North Carolina.

Widespread infection prompted the World Health Organization to declare a full-scale pandemic Thursday, but the agency noted that the virus generally causes only mild to moderate symptoms that most people can manage at home or with routine medical care.

Still, because the virus is so new, people have no immunity.

That makes vaccine development critical.

Six pharmaceutical companies supply flu vaccine to the United States, although most manufacture the drugs in Europe. All have received seed stock from the Centers for Disease Control and Prevention that will enable them to mass produce H1N1 vaccine, either cultivating in chicken eggs or with a new technology that uses other cells.

Manufacturers will begin churning out H1N1 vaccine later this summer after completing production of regular seasonal flu shots.

"There's no science issue he-

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re, but there are real manufacturing issues," said Jeffrey Frelinger, a professor of immunology at UNC-Chapel Hill.

Frelinger said scientists know how to make the vaccine, but they face additional puzzles about the proper dosage amounts and unknown health complications with a novel strain.

Ferrets first

Before being tried in humans, the vaccines will first be tested in ferrets to gauge safety. Health officials are eager to avoid the fiasco that occurred in 1976, when a vaccine was rushed to market to combat a new flu strain feared to become a pandemic.

That virus fizzled out, but the vaccine caused severe complications in some people.

"You can see the need to develop something quickly when you start talking about flu," said Dr. Wayne Harper, principal investigator with Wake Research Associates. But he said patient safety must not be compromised for expediency.

Still, there is a push to have vaccine available this fall, when many health officials fear the virus could roar back.

Harper said the two trials enlisting in the Triangle are already under way with recruitment efforts. The Wake Research site is the only one in North Carolina to test the two H1N1 vaccine candidates, and it is among few-

er than 100 test sites in the country, Grach said. She said she could not disclose which two drug makers are leading the local trials.

What recruits experience

Volunteers will be evaluated for health and other qualifications, Grach said, and those chosen to participate will be monitored for the vaccines' potency and side effects for at least a year.

Neither of the H1N1 flu vaccines being tested include live virus, so participants have no risk of developing influenza from them.

Kirby Dibb, 25, of Raleigh, said she participated in a trial of seasonal flu vaccine last fall at Wake Research, and said she also got her husband and other family members involved.

Dibb said she was given a health screening and interview, and then she was closely monitored for several days and weeks after getting the shot. She was also directed to call the research agency if she developed any symptoms, including flu, but she never got sick. She said she was paid \$450 for participating.

Now she is planning to volunteer for the H1N1 vaccine tests this summer — but it's not about the money. She said she wants to make a contribution to society.

"It's important to have the vaccine," Dibb said. "It's definitely a worthwhile cause."