



August 30, 2009

Delays in vaccine trials inject flu questions

Patti Singer
Staff writer

Imagine inviting a bunch of people to dinner and discovering that you don't have enough food.

Researchers testing vaccines against novel H1N1 have run into the scientific equivalent. Only they can't water down the soup.

They haven't been able to produce as much vaccine as originally anticipated.

Additionally, the Food and Drug Administration is reviewing protocols for the study.

The combination has put trials across the country about two weeks behind schedule.

Such a delay isn't unheard of, but it still means no answers to when a vaccine will be available, how it will be distributed, the number of doses and how costs to deliver the shots will be covered.

"The fact of the matter is this is really a big undertaking with a lot of unknowns," said John Ricci, a spokesman for the Monroe County Health Department.

"Having the answers sooner rather than later will be better. But it's understandable that we don't have them."

Three of the five trials at Rochester Clinical Research in Irondequoit, one of 15 testing sites across the country, are under way.

Another is scheduled to start in September and the last one in October. "There will be vaccine," said Patricia Larrabee, president and chief executive officer of RCR, "but it may not be in the quantity as early as we want it."

Health experts are watching how H1N1 behaves in other parts of the world in order to predict its effect here.

"Things may not hit till January," Larrabee said. "We may still be fine in the greater picture of things."

Studying vaccines

H1N1 is called a novel strain because it hasn't been seen before, but there's nothing new about making a flu vaccine. Each year the seasonal flu vaccine is changed to cover strains that health experts think will be prevalent.

The majority of the H1N1 vaccines are egg-based. Some studies, although not the one at RCR, are testing a virus-like particle for people who are allergic to eggs.

Larrabee said that manufacturers are getting less vaccine from each batch.

"Any time you're dealing with egg-based vaccine, the yield can be unpredictable. That's why there's so much research in ways other than egg-based vaccines."

Two of the current trials at RCR started July 27 and are testing injections of a dead virus. A different trial that started Aug. 3 and is looking at the effects of a nasal spray that uses attenuated virus, a live virus but in too small a dose to cause an infection. In both cases, volunteers get a dose and three weeks later receive a second dose.

So far, Larrabee said, there have been no adverse effects.

Additional trials are delayed because the FDA is reviewing their protocols. FDA spokeswoman Peper Long said the agency cannot comment on clinical trials because information that may be related to unapproved applications is confidential and exempt from the Freedom of Information Act.

FDA reviews aren't uncommon, Larrabee said. "They typically don't move as fast as we ask them to move."

Answers, please

Some of the logistical questions may stem from the delay in the studies; some may be from the nature of predicting the spread and severity of illness.

Some reports estimate deaths from H1N1 at 90,000 Americans, but approximately 36,000 Americans die from seasonal flu each year.

"We are eager to have the many questions we have, as does the public, answered," Ricci said. "We ask that people be patient with us until a little more of this gets sorted out."

Several scenarios have been discussed, said Ricci. Health departments could receive and distribute the vaccine, health departments and hospitals could each receive shipments, or doctors could order on their own.

When a vaccine is ready, current guidelines put pregnant women at the top of the list to receive it, followed by household caregivers for infants, health care and emergency services workers, children and young adults from 6 months to 24 years, adults ages 25 to 64 with medical conditions that put them at risk from complications from the flu, and those older than 65.

As for cost of the shots, the vaccine is free but there could be an administrative charge. Representatives of Excelsus BlueCross BlueShield and MVP Health Care said there's too much uncertainty to say whether or how any costs would be covered.

Ricci said that for seasonal flu vaccine, people without insurance typically attend a clinic run by the Health Department. That may be the case with H1N1, but "I can't emphasize often enough that all of this is preliminary."

Doctors get ready

As public health officials are planning for any eventuality, so is the family doctor.

Updates from federal, state and local officials go out regularly to the 100 physicians in the 20 practices of the Primary Care Network at the University of Rochester Medical Center, said medical director Dr. Jared Krackov. The practices range from family medicine to internal medicine and cover about 200,000 people.

Plans have to be more extensive than in previous years, Krackov said, because they need to account for seasonal flu and H1N1.

What if H1N1 turns out to be like a ballyhooed blizzard that leaves only a dusting?

"Our stance is we can never treat anything as a false alarm," Krackov said.

Nancy Blasio, a registered nurse and associate director for clinical quality assurance for the primary care network, said preparation includes educating patients that decisions are based on evidence and that there are variables.

"The more that you let them know that, it gives them confidence. They know there can be change, but the change is for a reason."

PSINGER@DemocratandChronicle.com
