

Govt calls for volunteers to test swine flu shots

July 22 2009, By LAURAN NEERGAARD , AP Medical Writer

(AP) -- The race is on: The government and vaccine makers are seeking thousands of volunteers, from babies to the elderly, to roll up their sleeves for the first swine flu shots - to test whether a new vaccine really will protect against this novel virus before its expected rebound in the fall.

On Wednesday the National Institutes of Health tapped a network of medical centers around the country to begin a series of studies, with the first shots to go into the arms of healthy adults, of any age, in early August. If there are no immediate safety concerns, such as allergic reactions, testing quickly would begin in children as young as 6 months.

The tests, plus additional research from vaccine manufacturers, are key as the government decides whether to offer [swine flu](#) vaccine to millions of Americans starting in mid-October - assuming that enough is produced by then - still a big question as the vaccine is proving hard to manufacture. Health authorities in other countries are looking to the U.S. studies, too, as they make their own plans.

It's crucial to test all ages. Unlike regular winter flu that is most dangerous to people over 65 and under 2, this new swine flu that has quickly spread around the globe seems to disproportionately target school-age children, teenagers and young adults.

Will the results come in time? "It's going to be very, very close," Dr. Anthony Fauci, director of NIH's National Institute of Allergy and

[Infectious Diseases](#), told The Associated Press.

"We are racing to provide them as much information as we possibly can," said Dr. Karen Kotloff of the University of Maryland School of Medicine, who is helping to lead the NIH study. She said doctors and other health workers already were asking about enrolling in the study themselves.

It promises to be a confusing fall, as doctors struggle to administer vaccine against the regular winter flu and tell patients to stay tuned for when and if they can later return for another shot or two of swine flu vaccine.

The test plan: All volunteers will get two swine flu shots, given 21 days apart. By early September, blood tests should show how much immune protection the initial dose triggered - and if a low-dose shot worked or a higher dose was needed. It will take another month to get information on the second shot.

Will parents want to enroll very young children? The NIH chose study hospitals with experience in testing vaccines on the very young, and "it's not a radically different vaccine from what they already get anyway," Fauci said.

The new swine flu strain is part of the H1N1 family of influenza viruses. We're used to that family. Some human strain of H1N1 has been included in regular influenza vaccine for 33 years, Fauci said - and the seasonal flu vaccine has a safe record for all ages. Yet because its a unique H1N1 strain, with genes that originated in swine, scientists worry that it may be harder than usual for a vaccine to trigger protection.

The swine flu vaccine "falls somewhere between a completely new vaccine and a strain change we do every year without clinical trials," said

Dr. John Treanor of the University of Rochester, a government vaccine adviser.

As for safety, the studies will track the typical vaccine side effects - redness, swelling, fever, allergic reactions - and any unexpected immediate reaction.

"We expect this vaccine to be no different than seasonal (flu) vaccine. It ought to be extremely safe," said Dr. William Schaffner, a vaccine specialist at Vanderbilt University.

But the studies won't be large enough to catch any very rare side effect. The last mass vaccination against a different swine flu, in the U.S. in 1976, was marred by reports of paralyzing Guillain-Barre syndrome. Scientists could never prove whether that link was real or coincidence, but all flu vaccine today comes with a warning about Guillain-Barre - and the government has pledged intense monitoring for rare reactions if mass swine flu vaccinations go forward.

Included in the NIH studies are vaccines made by France-based Sanofi-Pasteur and CSL Ltd. Also Wednesday, CSL began a much smaller study of its vaccine in Australia, where the company is based.

All five U.S. providers of [flu vaccine](#) - including Britain's GlaxoSmithKline, Swiss-based Novartis AG and maker of the only nasal-spray vaccine, Maryland-based MedImmune - also will conduct their own studies in several thousand more volunteers. Thursday, the Food and Drug Administration will review their testing plans.

The NIH's main study sites:

- University of Maryland School of Medicine, Baltimore.

- University of Iowa, Iowa City, Iowa.
- Saint Louis University, St. Louis, Mo.
- Baylor College of Medicine, Houston.
- Children's Hospital Medical Center, Cincinnati.
- Emory University, Atlanta.
- Group Health Cooperative, Seattle.
- Vanderbilt University, Nashville, Tenn.

Children's Mercy Hospital in Kansas City, Mo., and Duke University Medical Center in Durham, N.C., will partner with two sites for part of the research.

On the Net:

To search for "H1N1 influenza vaccine" trials:

<http://www.clinicaltrials.gov>

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Citation: Govt calls for volunteers to test swine flu shots (2009, July 22) retrieved 3 May 2024 from <https://medicalxpress.com/news/2009-07-govt-volunteers-swine-flu-shots.html>

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