One Vaccine Shot Seen as Protective for Swine Flu

By DONALD G. McNEIL Jr. Published: September 10, 2009

Defying the expectations of experts, clinical trials are showing that the new H1N1 swine flu vaccine protects with only one dose instead of two, so the vaccine supplies now being made will go twice as far as had been predicted.

That means it should be possible to vaccinate — well before the flu's expected midwinter peak — all the 159 million people that the Centers for Disease Control and Prevention estimate are in the high-risk groups: pregnant women, people under 24 years old or caring for infants, people with high-risk medical conditions and health-care workers.

Barring production delays, the government hopes to have in hand 195 million doses by year's end.

The first convincing trial results from a single 15-microgram dose in adults were published online Thursday afternoon by The New England Journal of Medicine. That trial was done in Australia, but the vaccine maker, CSL Limited, is under contract to supply millions of doses to the United States government, and the president of the company's American subsidiary said he expected its trials here to have similar results.

The H1N1 swine flu pandemic has now reached 168 countries. It arrived in the United States late in the spring and infected more than one million people. It did not fade out as seasonal flu does, but persisted, especially in summer camps. Nearly 600 people had died by the end of August, according to the disease control agency.

Cases are now surging again, especially in the Southeast where many schools and universities reopen earlier than in the rest of the country.

Dr. Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases, said trials now under way under the sponsorship of the National Institutes of Health were showing

that adults who got only a single dose were protected within 8 to 10 days, which he said "corroborates and confirms the exciting data" reported in the Australian study.

Robust protection produced so quickly in high-risk groups means lives will presumably be saved, Dr. Fauci said.

Costs will also be lowered by having a more efficient vaccine, he said, "but I can't give you a dollar figure."

Also, more vaccine could be available to poor countries that were largely left out of last spring's global scramble to sign vaccine makers to contracts. Experts have worried that rich countries would be protected this winter while poor ones — where people are more likely to die because of drug shortages and substandard hospital care — would bear the brunt of the pandemic.

"This is definitely a big deal," said Dr. John J. Treanor, a vaccine expert at the University of Rochester. "People had been planning for a scenario that would require two doses."

"This will take the edge off the nail-biting," Dr. Treanor added.

The results released Thursday were based on the first three weeks of a clinical trial. Healthy adults got one 15-microgram shot, and their blood was tested 21 days later. By that time, 97 percent of the 120 adults had enough antibodies to be considered protected. Another group that got 30-microgram doses had no greater protection.

There were no deaths or dangerous side-effects. Almost half of the participants reported sore arms or headaches, but that is normal with flu shots.

The American trials began about two weeks later, said Paul R. Perreault, president of CSL Biotherapies, the company's American subsidiary. "My experience with this tells me they shouldn't be any different," Mr. Perreault said.

Dr. Fauci said he would discuss the details of the N.I.H. trials at a news conference on Friday afternoon.

Seasonal flu shots are available now, and Federal officials are urging Americans to get one. Little or no swine flu vaccine will be available before late October. There have been no clinical trials of giving both shots at the same time, but the Centers for Disease Control and Prevention say simultaneous vaccinations are permissible as long as both vaccines are the killed-virus form

given by needle, rather than the weakened live-virus form given by nasal spray, and as long as the injections are in two different anatomical sites.

Experts had predicted for months that, because the H1N1 swine flu has never been seen before by human immune systems, it would take two doses, administered weeks apart, to get a “take” — antibody levels as high as those produced by regular flu shots.

The authors of the Australian study said the robust response implied that there was some previously unsuspected crossover protection from having had previous strains of H1N1 seasonal flus or from the H1N1 components of seasonal flu shots.

In mid-August, a Chinese vaccine maker, Sinovac Biotech, also reported that one shot of its vaccine gave protection against the flu. But because it released no data about the size of the dose or the composition of its vaccine, it was impossible for American experts to evaluate the claim.

Also, none of the 10 Chinese companies producing swine flu vaccine have licenses to sell in the United States, as CSL does, so their vaccines would have virtually no impact on the spread of the disease here.

Although the Australian trial was in healthy adults only, Dr. Treanor said he believed one dose of the new vaccine would prove effective in everyone from age 9 and up.

Pediatricians usually give two shots to children ages 6 months to 9 years who have never had a flu shot; the first primes the immune system and subsequent shots act as boosters that create new surges of antibodies, though slightly varied each year as strains mutate.

Infants under 6 months old are not normally given flu shots. Pregnant women are, and babies can inherit some temporary immunity from their mothers.

This article has been revised to reflect the following correction:

Correction: September 12, 2009

An article on Friday that described the effectiveness of one dose of swine flu vaccine referred incorrectly to federal recommendations on simultaneous vaccinations for swine flu and seasonal flu. The Centers for Disease Control and Prevention say simultaneous vaccinations are permissible as long as both vaccines are the killed-virus form given by needle, rather than the weakened live-virus form given by nasal spray,

and as long as the injections are in two different anatomical sites; health officials have not "issued no recommendations."