

## Bird Flu Vaccine Looks Safe, Effective

WEDNESDAY, May 10 (HealthDay News) -- French researchers report that a preliminary vaccine for the H5N1 strain of bird flu appears to be safe and produced an immune response in healthy people. It's not clear, however, that the vaccine would work in a real-life situation, or if it would be effective against other strains of bird, or avian, flu.

"The measures we used for the immune response are those used for the seasonal vaccine and there's quite a lot of data that suggest that these measures are likely to represent an effective vaccine," said Dr. Melanie Saville, co-author of the study and influenza franchise leader for clinical development at Sanofi Pasteur in Marcy l'Etoile, France.

"However, we don't know what level of antibody you need for protection against H5N1," Saville said, "and we can't say whether the results we see with the H5N1 vaccine would be similar for any other type of avian strain."

Sanofi Pasteur sponsored the study, which appears online Thursday in the journal *The Lancet*.

"This vaccine is more successful appearing than the last one that was published but it's not an overwhelming immunological response and we don't know if it works against cross strains," said Dr. Marc Siegel, author of *Bird Flu: Everything You Need to Know About the Next Pandemic* and clinical associate professor of medicine at New York University School of Medicine. "This has potential but it's not an automatic problem-solver."

The report came amid continued media and public frenzy over bird flu, which was the subject of a grim ABC television network movie *Fatal Contact: Bird Flu in America*, which aired Tuesday. The movie traces an outbreak of the H5N1 bird flu virus that begins in a Hong Kong market and mutates into a virus that's easily transmitted from human to human, resulting in a worldwide pandemic.

The U.S. government went so far as to issue a viewer's guide to the movie, stressing that the film was not a documentary and there is no influenza pandemic in the world at this time.

In a bit of unintended irony, the movie's plotline contends that researchers in France develop an effective vaccine -- but French authorities refuse to give it to other countries.

The current H5N1 virus has generated more fear than normal because of its virulence and ease of transmission among flocks of domesticated birds.

So far, bird flu has killed more than 100 people in nine countries, the lion's share in Vietnam, Indonesia and other parts of Asia. More than 200 million domestic fowl have been killed worldwide to help stem the spread of the illness.

Human casualties remain largely confined to Asia and to people who have had close and prolonged contact with infected birds, such as poultry farm workers. But one-third of Americans polled said they personally feared becoming infected with the bird flu.

That fear may be intensified with the looming threat that migrating birds may soon bring the virus to American shores.

In any event, efforts to come up with an effective vaccine continue to gather steam.

For the new trial, 300 healthy volunteers aged 18 to 40 received one of six vaccine formulations at various doses and with or without an adjuvant (a compound that increases the potency of other drugs).

Two doses of the vaccine (at either 30, 15 and 7.5 micrograms) were delivered 21 days apart.

All the formulations appeared to be safe. The most effective formulation was 30 micrograms with an adjuvant (66 percent of the participants developed sufficient antibodies), the researchers said.

"We saw responses in all the groups, although the best response was seen in 30 micrograms with the adjuvant," Saville reported.

For the smaller 7.5-microgram dose, more than 40 percent of volunteers developed antibodies.

"This is interesting from a dose-sparing perspective because, in a pandemic situation, you would want to have available as many doses as you possibly can," Saville said.

The vaccine was produced under an accelerated manufacturing process designed to make vaccine available as quickly as possible after a pandemic outbreak. "With everything going full speed, we would anticipate that it would take approximately three months to actually produce the vaccine according to the necessary standards," Saville said. "It's not business as usual."

U.S. Health and Human Services Secretary Mike Leavitt was recently quoted as saying that, with current capabilities, it would take at least six months to create a vaccine.

In an accompanying comment piece in the journal, Suryaprakash Sambhara, scientist from the U.S. Centers for Disease Control and Prevention, warned that it's unclear if the vaccine would work in the event of a real pandemic, and also pointed out that the vaccine response level was not optimal.

A growing chorus of experts, including Sambhara, are advocating that new methods be tested for production of an avian flu vaccine.

Siegel said: "It underlines the need for more research on using updated techniques. You can't see an emerging virus and start using this technique. It would take six to nine months. This underlines the need for more money and more research done on other methods."

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