

# Progress on bird flu vaccine

Researchers report new method that cuts production time in half

By Jonathan Bor | Sun Reporter

*June 12, 2008*

Researchers are reporting preliminary success with a vaccine against a possible "bird flu" pandemic, using a process they say could deliver the product in half the time required by older technology.

The milestone, experts said, also offers hope for speedier production of a vaccine against seasonal flu, potentially eliminating contamination problems and shortages that have cropped up in recent years.

Reporting today in a leading medical journal, scientists with [Baxter International Inc.](#) said their avian flu vaccine - which dispenses with the cumbersome process of growing vaccine in chicken eggs - was safe and triggered an immune response.

"This of course changes the whole game," Dr. Hartmut J. Ehrlich, a research and development chief for Baxter, said of the results. "We have shown that influenza vaccines can be produced in substrates different from chicken eggs."

As with any flu vaccine, it remains to be seen whether the vaccine would protect people in the face of a true pandemic. The vaccine has protected animals in earlier studies, but ethical constraints prevent researchers from exposing immunized humans to the virus to see what happens.

The Euro-Asian trial, described in today's *New England Journal of Medicine*, was conducted among 284 human subjects in Austria and Singapore and was designed to help Baxter win regulatory approval from European authorities. A parallel study involving the same vaccine has been under way in the United States to meet requirements of the Food and Drug Administration.

Although the U.S. trial results have not been published, "I can tell you the immune response was very, very similar," Ehrlich said in an interview. With slight differences, the two trials showed that the vaccine triggered an immune response in about 70 percent of volunteers.

It could take four or five more years of testing and data analysis to produce a vaccine ready for FDA review, Baxter officials said.

Rather than growing each vaccine in a fertilized egg, scientists produced them in large vats containing cell cultures. The process takes about 12 weeks, compared to the nearly half-year timetable for egg-based manufacture.

"If you can use a cell culture, it's like brewing beer," said Dr. Wilbur H. Chen, an assistant professor with the University of Maryland School of Medicine's Center for Vaccine Development. "You have a big vat full of cell culture. You stick virus in it and grow it."

Not only is egg culture slower, but problems with the availability and cleanliness of eggs can hamper production, said Chen, a safety monitor in the U.S. trial. People who are allergic to eggs can also develop a reaction to egg residue in the vaccine.

Concern about a possible replay of the 1918-1919 flu pandemic has persisted since the late 1990s, when an influenza strain infecting poultry in Hong Kong also spread lethally to humans.

Since then, the virus has sickened 381 people - most of them in Southeast Asia and Indonesia - with a kill rate of more than 60 percent.

So far, the virus has not shown the capability of spreading rapidly from person to person, the much-feared ingredient for a pandemic. Most of the human victims caught the virus from chickens, with just a few contracting it from family members living in close quarters.

Though some experts have begun to wonder whether the virus will ever develop the ability to spread through human populations, many also concede that a simple genetic change may be all that's needed. Such a change could occur if the seasonal and so-called H5N1 avian influenza viruses infect someone at the same time and begin swapping genetic information.

"Scientists in influenza research continue to be concerned that this is something that may very well happen, and we just don't know when and how it's going to happen," said Dr. Neal Halsey, a professor at the Johns Hopkins Bloomberg School of Public Health and director of its Institute for Vaccine Safety.

"This is significant progress in making a vaccine that would help protect us from what appears to be a virus that could cause a pandemic," said Halsey, adding that cell-based manufacture is key to delivering a vaccine reliably and fast enough to meet an emergency.

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