

Beware Live Virus Flu Vaccine Is Coming

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Despite recent studies reporting its efficacy in preventing flu, particularly in children, the latest live virus candidate vaccine against influenza (FluMist, Aviron, Mountain View, Calif), faces an uphill road on its way to licensure.

Several live virus influenza vaccines have been developed in the past 25 years or so; the agent of current interest was devised in the late 1980s by Hunein F. Maassab, PhD, a professor in the University of Michigan School of Public Health. In this vaccine, three of the six nonstructural viral genes are mutated so the virus is unable to replicate in the warmer temperatures of the lower respiratory tract. However, it proliferates in the cooler upper airways, where it stimulates mucosal antibodies and T-cell responses more effectively than does inactivated vaccine.

The live virus vaccine contains three temperature-sensitive mutant strains that are expected to circulate in the community during the next flu season. Two antigens on the influenza virus, hemagglutinin and neuraminidase, change over time, sometimes abruptly, allowing the virus to circumvent any immunity an individual may have acquired from earlier exposure to flu. Thus, the antigens in the live virus vaccine, like those in the killed virus vaccine, must be reformulated annually to meet the antigenic changes occurring in the wild-type virus.

Because to elicit an immune response the vaccine must cause infection, it is particularly effective in children, since they are immunologically naive compared with adults, whose immune response may be reduced by preexisting antibody. Immunization with the current inactivated influenza vaccine is recommended only for children aged 6 months and older with conditions that put them at high risk of serious complications from the disease, such as chronic pulmonary, cardiovascular, or metabolic disorders like asthma, diabetes, or renal dysfunction.

In June 1998, Aviron submitted a license application to the US Food and Drug Administration (FDA) and was confidently predicting that the vaccine would be available to physicians for the 2000-2001 flu season.

Two months later, the agency rejected the application, and the company has not yet resubmitted it. Aviron has said the FDA needed additional technical information, especially about the manufacturing processes and the facilities where the vaccine will be made. The company plans to make the vaccine in bulk in England and ship it to the United States for packaging..

One major concern has dogged live virus flu vaccine development from the beginning: the possibility that the attenuated vaccine virus could reassort with virulent wild-type virus and produce a new agent to which the population is susceptible. The result, some scientists hold, could well be an influenza pandemic paralleling that of 1918-1919.

It is difficult if not impossible to assess the probability for such adverse reassortment in nature. Human infection with the H5N1 chicken virus in Hong Kong has renewed the concern (JAMA.1998; 279:259-260 and 643-644). Still, the report noted, live virus flu vaccines have been widely used for many years in Central and Eastern Europe and in the former Soviet Union, and there has been no evidence suggesting increased prevalence or severity of disease through reassortment of the vaccine virus with wild-type virus.

Researchers expressed concern that the virus that goes into people, is not the virus that may come out of people or may recombine in the field, where intergenetic interactions may occur that cannot be predicted. The phenotype of the vaccine virus may be stable, but researchers have to be concerned about the possibility of interactions in the field. If you vaccinate using a trivalent vaccine with two different live influenza A strains, and then look at the viruses that come out of the recipient, there is a recombination rate of 50%. This indicates that there is great possibility for generating something novel. This issue hasn't been addressed very well.

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Dr. Mercola's Comments:

The flu vaccines will likely be approved and will be hyped quite a bit since they are administered via a nasal spray rather than injection. When they are approved, I highly advise to run, not walk or turn, away from these vaccines. The best that they could do for you is not hurt you. The worst is yet to be determined, but it could contribute to accelerated brain aging, immune impairment or development of some as yet to be determined irreversible chronic illness.

Micheal Belkin (who sent me this article) provides the following comments: This may be the most frightening vaccine development story yet. Keep in mind this is JAMA and the FDA restricted this vaccine. Like the US biological weapons lab at Plum Island in New York (which may have created the West Nile Virus threat where I live by putting experimental infected Nile virus material into the environment, which was picked up by birds) -- Frankenstein vaccine labs may be cooking up tomorrow's plagues in pursuit of today's profits.

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