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BIRD FLU: BE WARY, NOT PANICKED

Why we need a robust vaccine market

By Dr. Anthony S. Fauci

Seasonal influenza is generally not perceived as a major public health threat. Yet it causes 36,000 deaths and 200,000 hospitalizations in the United States each year, mostly among the elderly and other vulnerable populations.

Although vaccination is the most important countermeasure against the flu, fewer than one-third of Americans receive a flu shot each year. This bodes poorly for our ability to prepare for a much more serious global influenza pandemic.

If there were a crisis today similar to the 1918 outbreak of Spanish flu, in which 50 million lives were lost worldwide, virtually everyone would want to be vaccinated. But the infrastructure and vaccine-production capacity of this nation and the world are not prepared for such demand.

One way to bridge this gap is to increase the production capacity for seasonal flu vaccines. Then, if needed, these expanded manufacturing facilities could readily switch over to produce a pandemic vaccine.

Progress in this direction is already occurring.

During the 2004-05 flu season, only three vaccine-makers were licensed to distribute flu vaccine in the United States. This season, another manufacturer received FDA approval, and additional suppliers are expressing interest.

But growth in vaccine-production capacity must be matched with increased consumer demand. During the 2004-05 flu season, 4.5 million vaccine doses were not used and ultimately discarded. Companies forced to discard unused vaccine and absorb a financial loss would be reluctant to increase production capacity. Without a robust vaccine market, new and more efficient ways to manufacture influenza vaccines may not be aggressively pursued.

Because seasonal influenza viruses mutate slightly from year to year, vaccine must be reformulated for each flu season. Each year's vaccine protects people from viruses that are slightly different from those of the previous year, and adds protection to our existing immunity, accumulated from previous exposures and immunizations.

In contrast, pandemic influenza occurs when humans are exposed to a highly transmissible virus that is dramatically different from any virus they have previously encountered. In that event, it will be crucial to produce and distribute large quantities of vaccine matched to the circulating virus - without delay.

A pandemic could occur if one of the H5N1 avian flu viruses circulating in Asia, Europe, the Middle East, and Africa acquired the ability to transmit efficiently from person to person. The tendency of flu viruses to rapidly mutate makes it difficult to predict which strain could trigger a global pandemic. Nonetheless, public health officials, researchers, and industry have decided to proceed with the development of vaccines based on currently circulating bird flu strains. Such vaccines may not exactly match the viral strain that ultimately triggers a pandemic, but can serve as prototypes against a pandemic virus strain that may emerge later.

This effort serves two important purposes. As the H5N1 virus mutates, the prototype vaccines may offer enough protection to prime the immune system and reduce the severity of infection. This could buy precious time while a vaccine that closely matches the pandemic strain was produced and distributed. Producing prototype H5N1 vaccines also provides a trial run in developing the infrastructure and production capacity to manufacture enough vaccine should a worldwide pandemic ensue.

Once a safe and effective pandemic flu vaccine is developed, the challenge remains to rapidly produce and distribute the product. But again, unless consumer demand for seasonal flu vaccine increases significantly, vaccine-makers may be hard-pressed to sustain the production capacity that will ensure adequate supplies during a pandemic.

Yearly flu shots for most Americans would help create the infrastructure we need to prepare for pandemics, with the added advantage of providing immediate health benefits.

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