

Experts see bad, but not disastrous, flu season ahead

June 25 2009, By Val Brickates Kennedy

Pandemic. The word alone evokes images of societal chaos. But is that what we're really in for this fall, when the world faces its first official pandemic flu season since 1968?

Not exactly, public health experts say.

"The H1N1 virus could have a profound impact," Jennifer Nuzzo, an epidemiologist at the University of Pittsburgh Medical Center's Center for Biosecurity, told MarketWatch recently. "But we're not talking Hollywood pandemonium here."

That said, [health care](#) experts are also quick to note that twice as many people could get sick this [flu](#) season, as the recently identified H1N1 virus and [seasonal flu](#) bug work their ways through the population. The last official [flu pandemic](#) was declared in 1968 for the so-called Hong Kong flu, and although it yielded a relatively low death rate, it still managed to kill about 1 million worldwide.

Those who dismiss the H1N1 bug, also known as swine flu, as a hoax like to point out the death rate, so far, has been extremely low. Seasonal influenza generally kills about 36,000 Americans a year, while the H1N1 virus has only resulted in 87 confirmed deaths, as of June 24.

But those numbers are misleading, health experts say. They point out that the official death count includes only victims whose diagnoses were confirmed by a special laboratory test. The actual number of infections

is believed to be far higher, and should continue to climb as the virus gains traction.

Also on the minds of health care workers is that flu outbreaks tend to unfold with a wave of mild infections in the spring, followed by a more severe wave in the fall.

The fact that the H1N1 bug is a relatively new viral mash-up is also worrisome, experts say. Because of its novelty, most people appear to have no immunity to it, as opposed to seasonal flu viruses, which meander around the globe for years.

"More people could get sick from H1N1 than the seasonal flu because people have less immunity to it," Nuzzo said. "That's the conservative fear."

Another major concern is that the public could be bombarded simultaneously with two highly contagious bugs.

"The biggest worry is if there's an additive effect, it's just a lot more people in the health care system," said Dr. Paul Biddinger, associate director of the Harvard School of Public Health's Center for Public Health Preparedness. "Hospitals are already at capacity and ERs are well above it."

One scenario that most experts have ruled out, at least in the near term, is that the dreaded H5N1 virus will mutate over the next few months into an easily transmitted bug, creating a "perfect storm" pandemic.

Fortunately, H5N1, or avian flu, is still extremely difficult for humans to contract. But when they do, the effects are devastating.

To put the H5N1 virus in perspective, the most deadly pandemic the

world has seen in modern times was the so-called Spanish flu of 1918, which is believed to have killed up to 100 million people worldwide over the course of two years. The death rate from the seasonal flu is about 0.1 percent, while the Spanish flu had an estimated mortality rate of about 2 percent.

In comparison, the death rate for H5N1 is between 60 percent and 70 percent.

But the doomsday scenario that H5N1 could rapidly mutate into a highly contagious plague remains theoretical. While viruses have been known to turn on a dime, others end up burning out before they gain major momentum.

So what are health officials doing to help us prepare for the upcoming flu season?

According to the U.S. Department of Health and Human Services, which also oversees the Centers for Disease Control and Prevention and the Food and Drug Administration, the government has now shifted its pandemic planning focus from H5N1 to H1N1 for the upcoming flu season.

Seasonal flu still remains a priority. The government is still asking the five U.S.-licensed flu [vaccine](#) makers to supply the U.S. market with about 100 million doses of seasonal flu vaccine, a request on par with those of recent years. The five licensed makers include the U.K.'s AstraZeneca PLC and GlaxoSmithKline PLC; Switzerland's Novartis AG; France's Sanofi-Aventis; and Australia's CSL Ltd., according to the CDC.

For H1N1, however, the goal is to eventually have enough vaccine for all Americans, or about 300 million people. If the virus turns out to be more

aggressive than originally estimated, recipients may need two doses of vaccine, which translates into about 600 million doses, according to HHS.

In late May, HHS directed that \$1 billion that had been previously set aside to purchase pandemic vaccines be used to help pay for development of an H1N1 vaccine. The funds would also be used to purchase enough vaccine to inoculate the estimated 20 million members of the nation's so-called critical work force, which includes such people as emergency workers, health care personnel and utility plant operators, according to HHS spokeswoman Gretchen Michael.

One major hurdle is the length of time it takes to manufacture flu vaccine. Currently, flu vaccine is cultured in fertilized eggs. The process can take up to six months, a painfully long time to wait if a pandemic is at hand. It also requires millions of specialized eggs.

A newer process, which cultures the vaccine in animal cells, is far speedier, taking around 15 weeks.

Vaccine leader Novartis AG announced earlier this month that it has produced test batches of H1N1 vaccine using its cell-based technology. A Novartis spokeswoman said that new process was able to produce vaccine in just a little over a month.

With HHS' support, Novartis is in the process of building a cell-based manufacturing plant in North Carolina. The company already operates a similar facility in Marburg, Germany.

U.S. conglomerate Baxter International has also developed a cell-based process. In a statement to MarketWatch, a Baxter spokesman said the company was in discussions with the FDA about securing a license for a cell-based H1N1 vaccine, but did not want to speculate on the timetable.

In another departure from past practice, the U.S. government is also looking at ordering vaccines that contain immunity boosting agents called adjuvants, which can help stretch the vaccine supply.

Adjuvant vaccines are already in use abroad. But health care experts say U.S. regulators have been wary of them in the past because of lingering concerns that they can contribute to adverse reactions.

In its May announcement, HHS said that the \$1 billion being put towards an H1N1 vaccine would also be used for vaccines containing adjuvants. According to Michael, the agency would go for an adjuvant vaccine if it needed to procure unusually large amounts in a relatively short period of time.

How long will it take before an H1N1 vaccine is available?

Health officials have said that they hope by September they will have done enough human testing with the proposed vaccine to allow the product to go into mass production.

According to HHS, at current capacity rates, it will take through February 2010 to produce 600 million doses for the U.S. market. If an adjuvant is used, production would finish earlier, by the end of 2009.

In the meantime, HHS is working with health experts to determine who and how many Americans need to be immunized first.

"It's possible we could be way into the flu season before we have an adequate quantity of vaccine," Nuzzo said.

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