

H1N1 swine flu: Vaccine faces setbacks

Production issues mean fewer doses are likely to be ready in October, and younger recipients may need 2 shots

By William Mullen Tribune reporter

September 8, 2009

As the [swine flu](#) spreads across the Chicago area this fall, doctors at Elmhurst Clinic plan to quickly notify [pregnant](#) women, children and other high-risk patients about the need for a [vaccination](#), using the facility's new all-electronic database.

Yet questions about the vaccine's production leave them guessing about their ability to deliver the doses.

"We know the vaccine is coming, but we don't know when or in what quantities, which makes planning difficult," said Donald Lurye, a physician and CEO of the west suburban clinic.

The development of enough safe and effective vaccine is key to preparations for combating the expected proliferation of the H1N1 [virus](#). Around the world, the health industry is busy producing and testing it while officials race in other ways to prepare the nation's hospitals, clinics and public health agencies -- not to mention public schools and college campuses that are filling up once again.

But just as the extent of the [flu](#)'s eventual spread is unpredictable, it is unknown how quickly sufficient vaccine can be produced and whether millions of people may be delayed in getting it because of nagging production complications.

The vaccine has been slower to manufacture than expected, and fewer doses are likely to be ready in October. Doctors also are warning that each patient may require more than one dose. Another unknown is the public's willingness to take the vaccine, partly due to concerns about side effects and memories of a 1976 vaccine program that was abruptly halted.

Health officials are heavily promoting the inoculations. So far this year, fewer than 600 deaths have been attributed to H1N1 in the U.S., and swine flu was less lethal than feared during the southern hemisphere's recent winter months. But federal officials say that up to 40 percent of the U.S. population could develop symptoms during the coming winter flu season, and tens of thousands of deaths could result.

"This is one of those times that we should expect the worst and hope for the best," said Kenneth Alexander, a pediatric infectious disease specialist at the [University of Chicago](#) Hospitals. "We could be called alarmists, but I would rather be called an alarmist than be called a fool for being underprepared."

Ever since the 2009 H1N1 flu strain appeared in April in Mexico and quickly traveled to the U.S., scientists have been working to formulate a vaccine. Pharmaceutical companies around the globe are gearing up to mass produce it.

In the U.S. the vaccine is now undergoing testing for efficacy and safety at eight sites. The Obama administration last month urged an expedited timetable, but experts said the slow, deliberate methodology of perfecting the vaccine called for patience.

The vaccine is made by growing the live virus in millions of chicken eggs, then killing and purifying it. This strain, though, has not been growing as quickly as others. Manufacturers, who had hoped to release 100 million individual doses in October, have scaled back their initial estimate to between 45 million and 52 million.

The government's aim is to ultimately deliver 200 million or so doses throughout the flu season. The federal government is paying for production of the vaccine and will deliver it to 90,000 health-care provider sites around the country, said Melaney Arnold, spokeswoman for the Illinois Department of Public Health.

That includes just fewer than 3,000 sites in Illinois outside of [Chicago](#), which will oversee its own distribution program. City officials have said they would be selecting "an assortment" of sites based on criteria such as "geography and types of providers."

The vaccine will be administered both in public hospitals and private clinics, Arnold said. If circumstances warrant, she said, both her department and Chicago have contingency plans for mass inoculations, probably through schools, public clinics and churches and temples.

And because the H1N1 virus is "so new and novel to us," in Alexander's words, Americans younger than 50 have no natural immunity to it and may need two inoculations, health officials said.

The second dose may come two or three weeks after the first.

"We have the possibility or even the likelihood that it will be a two-dose series for children, at least, and perhaps for others," Thomas Frieden, [Centers for Disease Control and Prevention](#) director, said last week.

The two-dose possibility raises the question of whether 200 million doses will be enough for everyone on the initial priority list. On its Web site, the CDC said it does not expect a shortage but that there is "some possibility that initially the vaccine will be available in limited quantities."

The CDC has identified five population segments that should get the vaccine first: pregnant women, parents and caregivers of infants, health-care workers, children and youths from ages 6 months to 24 years and anyone age 25 to 64 who has a medical condition that puts them at higher risk.

That totals about 159 million people. If there is not enough vaccine, the priority list may be reduced to as few as 42 million, primarily by limiting inoculations to children ages 6 months to 4 years and to children and adolescents ages 5 to 18 who have complicating medical conditions.

The list is far different than CDC's priority list for normal seasonal flu, which is particularly deadly, for example, for elderly people with underlying diseases. But swine flu appears to be far less so, probably because elderly people have built up immunities from previous exposure to viruses similar to swine flu.

The other challenge for health experts is persuading skeptical or skittish Americans to get vaccinated. They have battled concerns that the vaccine actually causes the flu, which doctors say is impossible, and they are grappling with persistent memories of 1976's troubled flu vaccine program.

That year, [President Gerald Ford](#) ordered a massive drive to inoculate as many Americans as possible after a swine flu virus affected soldiers at an Army post on the East Coast.

But the vaccination program was halted after about 500 people out of 45 million inoculated came down with Guillain-Barre syndrome, a serious nervous system disorder.

Ever since, people have cited fear of possible side effects as a reason for not wanting a flu shot, though subsequent studies have shown that the chances of side effects are minuscule -- and far less serious than the risk of flu-related death.

"You have to weigh the risks," Alexander said. "We can't be 100 percent certain about some things, like the slight chance of adverse side effects in a flu vaccine, but we are 100 percent certain that the vaccine will work to stave off the flu."

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