Production of swine flu vaccine is way behind

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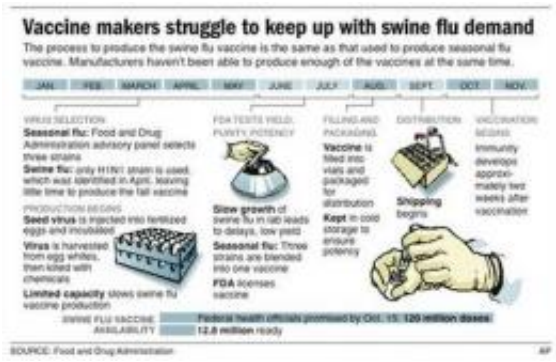

Graphic shows the timeline of flu vaccine production

(AP) -- The federal government originally promised 120 million doses of swine flu vaccine by now. Only 13 million have come through.

As nervous Americans clamor for the vaccine, production is running several weeks behind schedule, and health officials blame the pressure on pharmaceutical companies to crank it out along with the ordinary flu vaccine, and a slow and antiquated process that relies on millions of chicken eggs.

There have been other bottlenecks, too: Factories that put the precious liquid into syringes have become backed up. And the government itself ran into a delay in developing the tests required to assess each batch before it is cleared for use.

What effect the delays will have on the course of the outbreak is unclear, in part because scientists cannot say with any certainty just how dangerous the virus is, how easily it spreads, or whether it will mutate into a more lethal form.

"We're in this race against the virus, and only Mother Nature knows how many cases are going to occur over the next six to 10 weeks," said Michael Osterholm, a vaccine expert at the University of Minnesota.

In the meantime, many states have had to postpone mass vaccinations. Clinics around the country that managed to obtain doses of the vaccine have been swamped. And doctors are getting bombarded with calls from worried and angry parents.

"Nobody has it," said AnnMarie O'Connor, who waited more than four hours for the vaccine in Rockville, Md., standing in line with her two young children and about 1,000 other people. Health officials "said the shots would be here in early October. But where are they?"

Federal officials counsel patience, saying that eventually there should be enough of both vaccines for everyone who wants them.

"We wish we had better ways to produce vaccines perfectly predictably, but this is how influenza vaccine production often goes," Dr. Anne Schuchat, who heads the immunization and respiratory disease section at the Centers for Disease Control and Prevention, said last week.

The delays have led to renewed demands for a quicker, more reliable way of producing vaccines than the chicken-egg method, which is 50-year-old technology and involves injecting the virus into eggs and allowing it to feed on the nutrients in the egg white.

Since April, swine flu has killed more than 800 people in the U.S.,

including 86 children.

Federal officials initially projected that as many as 120 million doses of the vaccine would be ready to dispense by mid-October. They later reduced their estimate to 45 million. As of Tuesday, only 12.8 million were available. (Health officials say a single dose will protect adults, while children under 10 will need two doses.)

In a sign of how rapidly the virus is spreading, education officials said 198 schools in 15 states were closed Wednesday because of swine flu, with more than 65,000 students affected. That was up from 88 school closings the day before.

"Right now, the vaccine is in a race against the virus, and the virus is winning," Osterholm said.

The government now hopes to have about 50 million doses out by mid-November and 150 million in December, Dr. Nicole Lurie, assistant health and human services secretary for preparedness, told The Associated Press on Wednesday.

"By the end of November, I think we're going to be pretty well back on track," she said.

However, a study by Purdue University researchers said the vaccinations will probably come too late to significantly reduce the number of infections. The study, published last week, predicted that infections would peak in late October and that by the end of the year, 63 percent of the U.S. population will have caught the virus.

The blame for the delays has been placed in part on the chicken-egg technology. It is a slow process, and the pressure on manufacturers to produce two vaccines at the same time - for both swine flu and ordinary

flu - has made it even slower.

Also, the virus on which the swine flu vaccine is based was found to reproduce very slowly in eggs - much more slowly than the ordinary flu virus. Health and Human Services Secretary Kathleen Sebelius, who on Wednesday was grilled about the delays by the Senate Homeland Security Committee, said the problem has been fixed.

The U.S. government is funding newer technologies that hold the promise of a more reliable and expandable vaccine supply.

"We need a man-to-the-moon effort for flu vaccine if we don't want to find ourselves in the same position in the future," Osterholm said.

Flu vaccines are not nearly as profitable as other kinds of drugs, and most of the biggest vaccine makers have little incentive to switch from a method with which they are familiar.

At its two plants in the Pocono Mountains town of Swiftwater, Sanofi Pasteur, the top U.S. supplier of seasonal vaccine, is churning out more than 75 million doses of swine flu vaccine and 50 million doses of the winter flu variety.

Sanofi spokeswoman Donna Cary said egg-based production of flu vaccine is "tried and true" and will probably remain the dominant method for years to come.

"If it weren't for the egg-based process, we wouldn't be able to respond to this pandemic," she said.

More than 30 farms in the eastern United States are under long-term contract to provide eggs for vaccines, tending 9 million to 12 million chickens.

Once the fertilized eggs arrive at the vaccine plant, the flu virus is injected into them and allowed to multiply for several days. Then the eggshells are cracked; the virus-laden fluid is extracted, the flu virus is killed and the substance is purified. The inactivated strain is tested to determine purity, potency and yield.

From start to finish, the process takes about six months. In normal years, that is usually enough time to get the vaccine to anyone who wants it. But in an all-out epidemic, egg-based production is incapable of producing huge batches quickly.

The government has awarded a $487 million contract to Novartis for a plant in North Carolina that will make flu vaccine by growing the virus inside animal cells, preferably from mammals. The plant is expected to be up and running by 2011 or 2012.

Also, Protein Sciences Corp. of Meriden, Conn., landed a five-year, $147 million contract to develop a vaccine using its recombinant technology - flu proteins grown in insect cells. The hope is that the first doses would be available within 12 weeks of the beginning of a pandemic. That is about twice as fast as flu vaccine produced from eggs.

"I think you're going to see these new technologies come on board rapidly, especially given what's happened this year," said Paul Radspinner, president and chief executive of FluGen Inc., a Madison, Wis., company working on several new vaccine technologies of its own.

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