

# Swine Flu Campaign Waits on Vaccine

Only Third of Supply Is Expected for First Round of Vast Effort

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Government health officials are mobilizing to launch a massive swine flu vaccination campaign this fall that is unprecedented in its scope — and in the potential for complications

The campaign aims to vaccinate at least half the country's population within months. Although more people have been inoculated against diseases such as smallpox and polio over a period of years, the United States has never tried to immunize so many so quickly.

But even as scientists rush to test the vaccine to ensure it is safe and effective, the campaign is lagging. Officials say only about a third as much vaccine as they had been expecting by mid-October is likely to arrive by then, when a new wave of infections could be peaking.

Among the unknowns: how many shots people will need, what the correct dosage should be, and how to avoid confusing the public with an overlapping effort to combat the regular seasonal flu.

To prepare, more than 2,800 local health departments have begun recruiting pediatricians, obstetricians, nurses, pharmacists, paramedics and even dentists, along with a small army of volunteers from churches and other groups. They are devising strategies to reach children, teenagers, pregnant women and young and middle-aged adults in inner cities, suburban enclaves and the countryside.

"This is potentially the largest mass-vaccination program in human history," said Howard Markel, a professor of medical history at the University of Michigan who is advising the Centers for Disease Control and Prevention as it spearheads the effort.

Public health officials describe the effort as crucial to defend against the second wave of the Northern Hemisphere's first influenza pandemic in 41 years.

As schools reopen, the number of cases could jump sharply within weeks, sparking a second wave potentially far larger than the outbreak last spring. Although the swine flu appears no more dangerous than the typical seasonal flu, the new virus — known as H1N1 — is likely to infect many more people because most have no immunity against it.

The vaccine effort carries political risks for the Obama administration. "If the outbreak fizzles, they will be susceptible to being criticized for spending billions of dollars," said Harvey V. Fineberg, president of the National Academy of Sciences' Institute of Medicine,

which advises Congress about medical issues. “On the other hand, if this outbreak is early and severe and there isn’t enough vaccine, they’ll be criticized for under-preparation.”

Officials stress that they are proceeding cautiously. A final decision to move forward will not be made until they get the results of clinical trials — testing to determine safety and dosing — and assess the virus’s threat. But officials are confident the vaccine will pass muster and expect a campaign will be launched as soon as manufacturers deliver the first vials.

“There’s little doubt we’re going to vaccinate people,” said Anthony S. Fauci of the National Institute of Allergy and Infectious Diseases, who is leading the government’s testing of the vaccine. “Who and when and exactly how — we have to figure out.”

The campaign is haunted by memories of the government’s ill-fated 1976 effort to vaccinate against swine flu. The epidemic fizzled, but the vaccine was given to 40 million people and blamed for causing a rare paralyzing disorder known as Guillain-Barré Syndrome

Another wild card will be whether the vaccine will be delivered with an “adjuvant” to boost its effectiveness or stretch limited supplies into more doses. Adjuvants have been used in Europe, but the Food and Drug Administration has not authorized their use in the United States.

“This is an overreaction,” said Barbara Loe Fisher of the National Vaccine Information Center, which opposes many vaccine policies. “There is no national security threat here. Why are we operating like this? This is not polio. This is not smallpox.”

Fears and misinformation about the vaccine are circulating, including inaccurate claims that it will be mandatory.

“I’m very concerned about the dangers of vaccines,” said Janice Smith, 58, of Misawaka, Ind., who attended a public hearing Aug. 15, one of a series of meetings the CDC has sponsored to gauge public sentiment about the vaccine.

Authorities are adamant that vaccination will be voluntary, and they say there is no reason to think the vaccine will be any less safe than the usual flu vaccine. An adjuvant will be used only if necessary and proven safe, they say.

To address concerns of pregnant women and parents with young children, some vaccine is being produced without a mercury additive. And because the short-term studies can identify only common, immediate side effects, the CDC will step up monitoring for rarer, serious complications such as Guillain-Barré.

“We’re putting into place systems that are as good as we can have to identify problems quickly if they do occur,” CDC Director Thomas R. Frieden said.

On Friday, officials reported that no “red flags regarding safety” had emerged in the clinical trials. “We are continuing oversight on the quality and safety of the vaccine being produced, and the production process itself,” said Jesse Goodman of the FDA. “That’s going well so far, but our oversight is continuing.”

In the meantime, local officials are drafting plans tailored to their communities. The shots in the arms and squirts up the nose will happen in schools, medical offices, hospitals, public

health clinics, workplaces, drug stores and at mass vaccination events, possibly including drive-through clinics in parking lots where people would stick their arms out their car windows for a stab.

“It is clearly what we would call an all hands on deck,” said James Blumenstock of the Association of State and Territorial Health Officials. “We’re not starting from scratch, but we also don’t have everything on the shelf that we can just pull off and put in place. It’s a full-court press in moving forward to have everything in place when we’re ready to go.”

In Maryland, officials estimate that 2.9 million people fall into the priority groups for the vaccine; Virginia estimates the number at 2.5 million and the District at 225,000. The national total is about 159 million people.

Public health departments “have suffered from decades of neglect and are now facing a fiscal crisis in many places where they have had to lay staff off, or furlough staff or freeze hiring,” Frieden said. “So H1N1 has not come at a particularly good time.”

Setting priorities for delivering the vaccines will bring other complications. The elderly, usually first in line for flu shots, will not be this time because they seem more resistant to the virus. But they remain a top priority for the seasonal shots.

Schools considering giving shots to children are making plans to get permission from parents and have to determine how best to line up anxious, rambunctious students.

Everyone who gets a swine flu shot may need a booster several weeks later, potentially causing mix-ups about who got which shot when.

But Frieden and other outside observers expressed confidence that the program would be safe and successful.

The federal government has spent close to \$2 billion to buy up to 195 million doses of vaccine and adjuvant, including the standard shots and the newer FluMist nasal spray vaccine made by MedImmune of Gaithersburg.

The government is prepared to buy enough to vaccinate every person — 600 million doses all together — if the pandemic or demand warrants it. That could increase the cost to \$5 billion for the vaccine alone. It would cost at least \$9 billion to administer the vaccine to the entire population, according to the Association of State and Territorial Health Officials.

Although five companies are racing to produce as much vaccine as possible, the first batches are not expected for two months, in part because the virus grew at about half the projected rate. Production appears to be increasing, but the first 45 million to 52 million doses — about a third of what officials were anticipating — won’t be ready until mid-October, with about 20 million doses a week expected after that to continue the campaign through the winter.

Experts are uncertain whether they will face a shortage of vaccine because of high demand or will have plenty of vaccine but little interest.

“People’s enthusiasm will depend largely on what they see happening around them,” Fauci said. “If we get into the fall season and we don’t see an explosion of cases, people will be less enthusiastic. If they see a lot of young people and kids getting sick, people will be very

enthusiastic about getting vaccinated.”

The CDC is formulating a \$4.8 million multimedia campaign to encourage people to get vaccinated and help alleviate concerns and confusion, including radio and television public service announcements, print ads, and messages delivered via Twitter, RSS feeds and video podcasts on YouTube

Although the vaccine will be free, providers could charge about \$15 to administer it — a fee that will be covered by Medicare and many health insurance plans.

Experts also worry the swine flu will divert attention from the seasonal flu, which can cause serious illness. Officials will launch the seasonal flu vaccine campaign Sept. 10 — about a month early in the hopes of vaccinating as many people as possible before the swine flu campaign. The more people who get both vaccines, the less likely the swine flu virus will mingle with one of the others to produce a more dangerous mutant.

“We really don’t want those ugly viruses mixing together,” said Kim Elliott of the Trust for America’s Health, a private nonprofit research and advocacy group.

*Staff writers Rachel Saslow in Washington and Kari Lydersen in Chicago contributed to this report.*

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