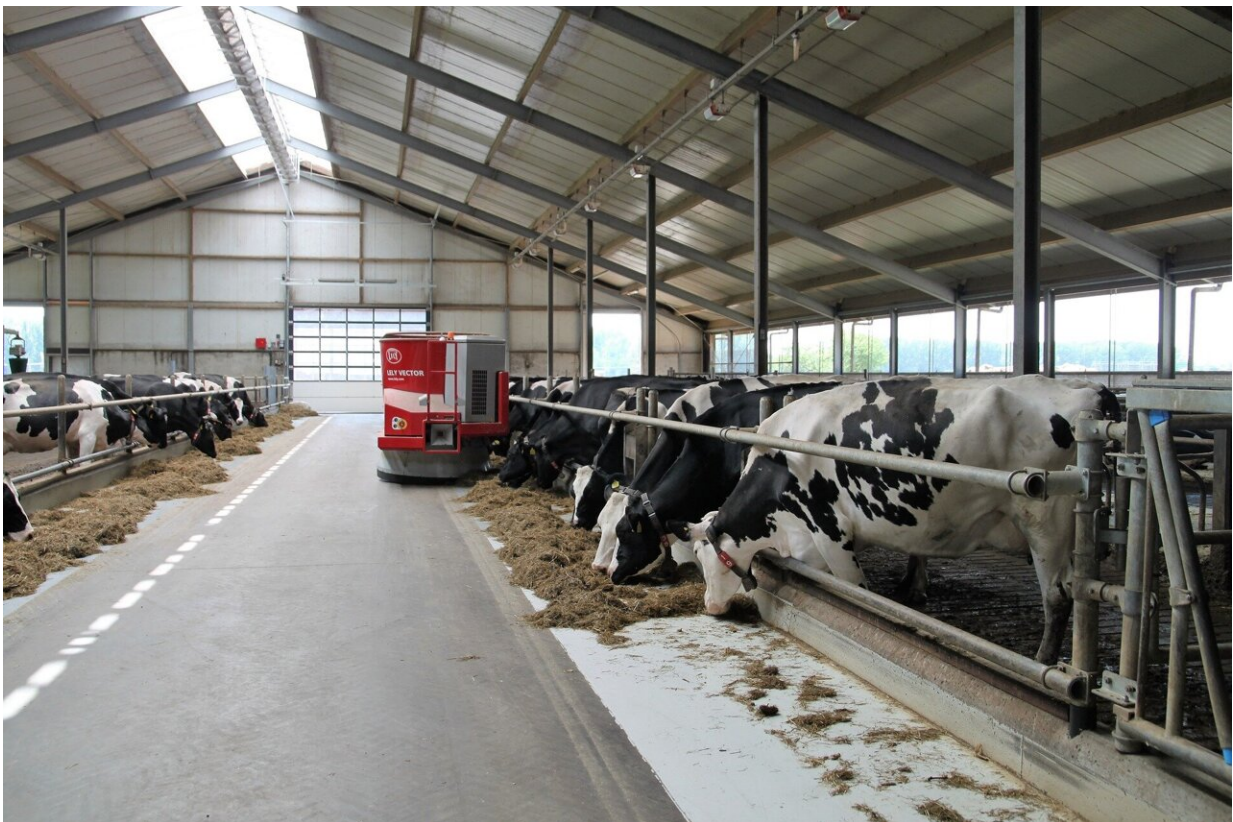


Bird flu tests are hard to get: Researchers warn US could be caught off guard by a pandemic

June 14 2024, by Amy Maxmen, Arthur Allen, KFF Health News



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Stanford University infectious disease doctor Abraar Karan has seen a lot of patients with runny noses, fevers, and irritated eyes lately. Such

symptoms could signal allergies, COVID, or a cold. This year, there's another suspect, bird flu—but there's no way for most doctors to know.

If the government doesn't prepare to ramp up H5N1 [bird flu](#) testing, he and other researchers warn, the United States could be caught off guard again by a pandemic.

"We're making the same mistakes today that we made with COVID," Deborah Birx, who served as former President Donald Trump's coronavirus response coordinator, said June 4 on CNN.

To become a pandemic, the H5N1 [bird flu virus](#) would need to spread from person to person. The best way to keep tabs on that possibility is by testing people.

Scientifically speaking, many diagnostic laboratories could detect the virus. However, red tape, billing issues, and minimal investment are barriers to quickly ramping up widespread availability of testing. At the moment, the Food and Drug Administration has authorized only the Centers for Disease Control and Prevention's bird flu test, which is used only for people who work closely with livestock.

State and federal authorities have detected bird flu in [dairy cattle](#) in 12 states. Three people who work on separate dairy farms tested positive, and it is presumed they caught the virus from cows. Yet researchers agree that number is an undercount given the CDC has tested only about 40 people for the disease.

"It's important to know if this is contained on farms, but we have no information because we aren't looking," said Helen Chu, an infectious disease specialist at the University of Washington in Seattle who alerted the country to COVID's spread in 2020 by testing people more broadly.

Reports of untested sick farmworkers—as well as a maternity worker who had flu symptoms—in the areas with H5N1 outbreaks among cattle in Texas suggest the numbers are higher. And the mild symptoms of those who tested positive—a cough and eye inflammation, without a fever—are such that infected people might not bother seeking medical care and, therefore, wouldn't be tested.

The CDC has asked farmworkers with flu symptoms to get tested, but researchers are concerned about a lack of outreach and incentives to encourage testing among people with limited job security and access to health care. Further, by testing only on dairy farms, the agency likely would miss evidence of wider spread.

"It's hard to not compare this to COVID, where early on we only tested people who had traveled," said Benjamin Pinsky, medical director of the clinical virology laboratory at Stanford University. "That left us open to not immediately recognizing that it was transmitting among the community."

In the early months of COVID, the rollout of testing in the United States was catastrophically slow. Although the World Health Organization had validated a test and other groups had developed their own using basic molecular biology techniques, the CDC at first insisted on creating and relying on its own test. Adding to delays, the first version it shipped to state health labs didn't work.

The FDA lagged, too. It didn't authorize tests from diagnostic laboratories outside of the CDC until late February 2020.

On Feb. 27, 2020, Chu's research lab detected COVID in a teenager who didn't meet the CDC's narrow testing criteria. This case sounded an alarm that COVID had spread below the radar. Scaling up to meet demand took time: Months passed before anyone who needed a COVID

test could get one.

Chu notes this isn't 2020—not by a long shot. Hospitals aren't overflowing with bird flu patients. Also, the country has the tools to do much better this time around, she said, if there's political will.

For starters, tests that detect the broad category of influenzas that H5N1 belongs to, called influenza A, are FDA-approved and ubiquitous. These are routinely run in the "flu season," from November to February. An unusual number of positives from these garden-variety flu tests this spring and summer could alert researchers that something is awry.

Doctors, however, are unlikely to request influenza A tests for patients with respiratory symptoms outside of flu season, in part because health insurers may not cover them except in limited circumstances, said Alex Greninger, assistant director of the clinical virology laboratory at the University of Washington.

That's a solvable problem, he added. At the peak of the COVID pandemic, the government overcame billing issues by mandating that [insurance companies](#) cover tests, and set a lucrative price to make it worthwhile for manufacturers. "You ran into a testing booth on every other block in Manhattan because companies got \$100 every time they stuck a swab in someone's nose," Greninger said.

Another obstacle is that the FDA has yet to allow companies to run their influenza A tests using eye swabs, although the CDC and public health labs are permitted to do so. Notably, the bird flu virus was detected only in an eye swab from one farmworker infected this year—and not in samples drawn from the nose or throat.

Overcoming such barriers is essential, Chu said, to ramp up influenza A testing in regions with livestock. "The biggest bang for the buck is

making sure that these tests are routine at clinics that serve farmworker communities," she said, and suggested pop-up testing at state fairs, too.

In the meantime, novel tests that detect the H5N1 virus, specifically, could be brought up to speed. The CDC's current test isn't very sensitive or simple to use, researchers said.

Stanford, the University of Washington, the Mayo Clinic, and other diagnostic laboratories that serve hospital systems have developed alternatives to detecting the virus circulating now. However, their reach is limited, and researchers stress a need to jump-start additional capacity for testing before a crisis is underway.

"How can we make sure that if this becomes a public health emergency we aren't stuck in the early days of COVID, where things couldn't move quickly?" Pinsky said.

A recent rule that gives the FDA more oversight of lab-developed tests may bog down authorization. In a statement to KFF Health News, the FDA said that, for now, it may allow tests to proceed without a full approval process. The CDC did not respond to requests for comment.

But the American Clinical Laboratory Association has asked the FDA and the CDC for clarity on the new rule. "It's slowing things down because it's adding to the confusion about what is allowable," said Susan Van Meter, president of the diagnostic laboratory trade group.

Labcorp, Quest Diagnostics, and other major testing companies are in the best position to manage a surge in testing demand because they can process hundreds per day, rather than dozens. But that would require adapting testing processes for their specialized equipment, a process that consumes time and money, said Matthew Binnicker, director of clinical virology at the Mayo Clinic.

"There's only been a handful of H5N1 cases in humans the last few years," he said, "so it's hard for them to invest millions when we don't know the future."

The government could provide funding to underwrite its research, or commit to buying tests in bulk, much as Operation Warp Speed did to advance COVID vaccine development.

"If we need to move to scale this, there would need to be an infusion of money," said Kelly Wroblewski, director of infectious disease programs at the Association of Public Health Laboratories. Like an [insurance policy](#), the upfront expense would be slight compared with the economic blow of another pandemic.

Other means of tracking the H5N1 virus are critical, too. Detecting antibodies against the bird flu in farmworkers would help reveal whether more people have been infected and recovered. And analyzing wastewater for the virus could indicate an uptick in infections in people, birds, or cattle.

As with all pandemic preparedness efforts, the difficulty lies in stressing the need to act before a crisis strikes, Greninger said.

"We should absolutely get prepared," he said, "but until the government insures some of the risk here, it's hard to make a move in that direction."

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Citation: Bird flu tests are hard to get: Researchers warn US could be caught off guard by a pandemic (2024, June 14) retrieved 23 June 2024 from <https://medicalxpress.com/news/2024-06-bird-flu-hard-caught-pandemic.html>

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