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Democracy Dies in Darkness

What went wrong with the coronavirus tests in the U.S.

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Since Renee Schwartz developed shortness of breath and a severe cough two weeks ago, she has been trying desperately to get a coronavirus test. She has already been tested for the flu — she was negative — and other problems have been ruled out. But while her doctor thinks a test is warranted, she told Schwartz she does not have access to any tests.

“I feel like crap,” said Schwartz, 60, of North Hills, Calif. “I want to know, why can’t I get this test?”

While the stories of people who are sick but can’t get tested get widespread attention, President Trump presented the situation very differently on a Friday afternoon visit to the Centers for Disease Control and Prevention in Atlanta.

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"Anybody that needs a test gets a test. Anybody that needs a test. They are all set; they have them out there," Trump said. "As of right now, and yesterday, anybody that needs a test can get one."

Production is ramping up, but tests — and the labs and equipment necessary to run them — are still very limited. Even where test kits are available, many states are following strict criteria for who should be tested to avoid overwhelming their labs.

Interviews with a dozen laboratory experts and government health officials reveal a six-week series of glitches, missed opportunities and delays that contributed to the shortage.

"They've simply lost time they can't make up. You can't get back six weeks of blindness," said Jeremy Konyndyk, who oversaw the international response to Ebola during the Obama administration and is a senior policy fellow at the Center for Global Development. "To the extent that there's someone to blame here, the blame is on poor, chaotic management from the White House and failure to acknowledge the big picture."

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The problems started in early February, at a CDC laboratory in Atlanta.

A technical manufacturing problem, along with an initial decision to test only a narrow set of people and delays in expanding testing to other labs, gave the virus a head start to spread undetected — and helped perpetuate a false sense of security that leaves the United States dangerously behind.

Nineteen people are dead, and there are more than 300 known cases of the novel coronavirus in the United States and undoubtedly many more cases that have not been detected.

In late December, when reports of a new virus causing mysterious pneumonia began to trickle out of Wuhan, China, public health experts went on high alert. One of the first needs was to develop a test so that governments across the world would have the ability to track the spread of the virus.

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China developed its own test. Leading laboratories in Germany published their own version, which was adopted by the World Health Organization. Many countries, including the United States, developed their own tests.

The traditional U.S. strategy for devising new diagnostic tests starts with the CDC. That is supposed to ensure new tests are accurate and reliable, but it also meant that other parallel approaches were not aggressively pursued.

Scott Gottlieb, former Food and Drug Administration commissioner in the Trump administration, said, “The key in a crisis like this is to take an all-of-the-above approach, whether we’re dealing with diagnostics or therapeutics.” That responsibility, he said, was up to other parts of the administration, such as the Department of Health and Human Services or the FDA.

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The CDC shared the details of the U.S. test publicly on Jan. 24.

A week later, the United States declared a public health emergency, a process designed to speed the development of diagnostic tests and other medical products. The CDC received the first “emergency use authorization” to make and distribute its test to the backbone of the public health system in the United States — mostly state labs.

But the emergency policy, intended to keep quality high, also discouraged hospital labs from quickly developing in-house tests. They would need specific approval from the FDA to do so.

“Since CDC and FDA haven’t authorized public health or hospital labs to run the tests, right now #CDC is the only place that can. So, screening has to be rationed,” Gottlieb tweeted on Feb. 2.

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The CDC manufactured kits, and on Feb. 6 and 7, 90 test kits were shipped to the public health labs. Some labs began to have trouble with the test. On Feb. 12, the CDC announced the test was providing inconclusive results in some laboratories. The problem was in one of the three components of the test.

It involved a part of the third component intended to be a backstop — a double-check so that when labs get a negative result, they can trust it. A federal official, who spoke on the condition of anonymity because there is an ongoing investigation, said the problem may have been a design flaw or contamination in a CDC lab when the tests were being produced.

Some critics have questioned why the CDC didn't switch to tests being used by other countries as soon as the problems arose, but the official said it would have taken longer to apply for a new authorization from the FDA and validate and manufacture a new test than it would to fix a test they knew worked in their own lab.

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Demand for testing was manageable at the time — in part because the CDC criteria for who should get tested required recent travel to China or close contact with a confirmed case. That narrow testing identified few infections, reinforcing the idea that the country had enough tests.

But epidemiologists advising the CDC already had been debating when to begin broader testing to see if the virus was circulating in the community, said Jeffrey Engel, executive director of the Council of State and Territorial Epidemiologists. Narrow testing basically guaranteed that the United States would remain unaware of whether the virus was already circulating among people who thought they had a cold or the flu.

On Feb. 13, HHS Secretary Alex Azar testified before Congress that a limited five-city pilot would begin to add coronavirus to the usual flu surveillance system to see whether "there is broader spread than we have been able to detect so far." But the plan was delayed because coronavirus tests weren't available.

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Academic hospitals, which have laboratories that routinely develop tests to use on their patients, began to get increasingly anxious about the nation being dependent on the CDC lab. They considered pursuing FDA approval for their tests but complained they didn't have the resources or expertise — or access to crucial materials such as the virus itself — for the complicated application process required during a public health emergency.

"When the CDC test was delayed, then the cases started appearing outside of China, there should have been a quicker response to get diagnostic testing going" by easing regulations on hospital labs, said Melissa Miller, director of the clinical molecular microbiology laboratory at the University of North Carolina at Chapel Hill School of Medicine.

During the Zika outbreak, some laboratories developed their own tests and got letters from the FDA notifying them that their tests had not been approved. Even as coronavirus testing remained limited nationwide, the CDC reminded hospitals on Feb. 18 that they shouldn't do their own testing without an "emergency use authorization" from the FDA.

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People experienced with working on other outbreaks have said that more flexibility was necessary to get more labs and companies testing.

"I don't think anyone is used to dealing with a pandemic like this. None of us alive have ever witnessed a pandemic like this, or what it could become. I think traditional ways of looking at how to develop diagnostics, therapeutic . . . have to be thought of differently, or we'll never get things out fast enough," said Mark Miller, chief medical officer of bioMérieux, a leading diagnostics company that aims to launch a test by the end of March.

As days went by, public health labs became increasingly desperate and on Feb. 25 requested special permission from the FDA to develop their own tests. The agency accepted the request. But along with the CDC, it also found a workaround, allowing a partial CDC test to be used. New test kits began to be sent out in the following days, with two of the three original components.

Almost as soon as testing capabilities came online, labs found cases of coronavirus. A week ago, a person in Oregon who had been sick since Feb. 19 tested positive — hours after state officials got their CDC test up and running. In Washington state, one of the cases identified was a teenager who went to the doctor with ordinary flu symptoms; his swab was submitted through surveillance testing that was only possible after the testing capabilities came online.

On Feb. 29, the FDA finally announced a new policy to make it easier for hospital laboratories to develop their own tests. "This outbreak and our response is dynamic and evolving," said Stephanie Caccomo, a spokeswoman for the FDA. "As the situation changes, we are being flexible as we execute policies intended to protect public health."

"Most laboratories were anticipating a more rigorous FDA stance, and had not been leaning forward for tests that could have been made more useful," a federal health official said. "We were working under the rubric and framework they set in place, and had they known things could be more flexible," labs might have moved forward faster.

Public health labs had received tests for up to 75,000 people by Friday. As of Friday night, more than 1.1 million tests had been shipped to nonpublic health labs including academic medical centers and commercial laboratories, officials said. The administration said 4 million more tests will be shipped in the next several days.

Quest Diagnostics announced its coronavirus testing would be available Monday. LabCorp announced its tests were available Thursday evening.

As testing problems are fixed, public confusion remains — as does frustration about uneven access to testing.

A California nurse who is sick and cared for a patient confirmed to be infected with the coronavirus said in a statement Thursday that she was still waiting for permission to be tested.

“This is not the ticket dispenser at the deli counter; it’s a public health emergency!” the nurse, who was not named, wrote in a statement shared by the California Nurses Association. “I am a registered nurse, and I need to know if I am positive before going back to caring for patients. I am appalled at the level of bureaucracy that’s preventing nurses from getting tested. That is a health care decision my doctor and my county health department agree with. Delaying this test puts the whole community at risk.”

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