‘It’s Just Everywhere Already’: How Delays in Testing Set Back the U.S. Coronavirus Response

Description

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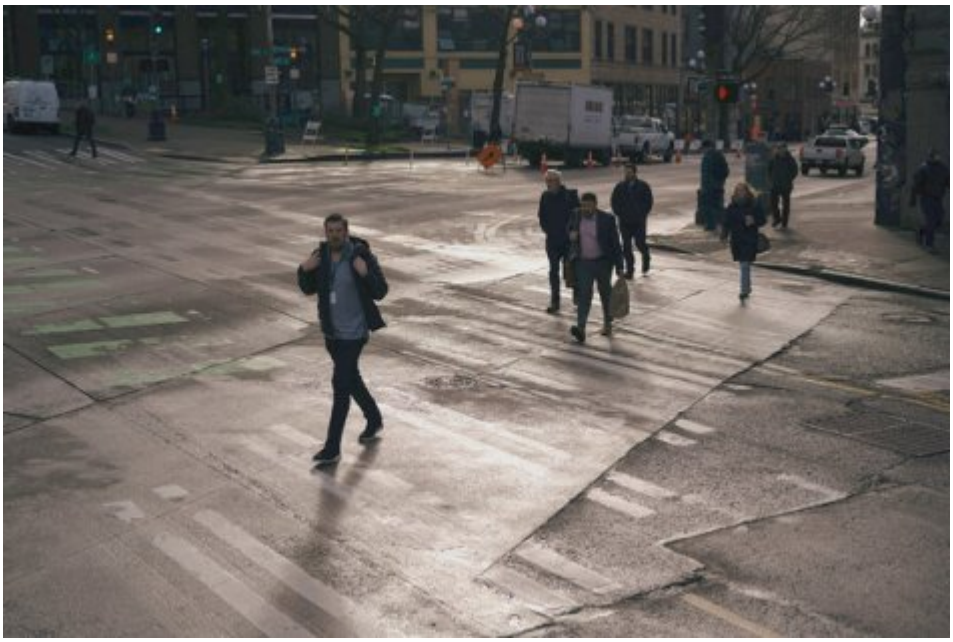
A series of missed chances by the federal government to ensure more widespread testing came during the early days of the outbreak, when containment would have been easier.



A research project in Seattle tried to conduct early tests for the new coronavirus but ran into red tape before circumventing federal officials and confirming a case. Credit…Grant Hindsley for The New York Times

By Sheri Fink and Mike Baker

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Dr. Helen Y. Chu, an infectious disease expert in Seattle, knew that the United States did not have much time.

In late January, the first confirmed American case of the coronavirus had landed in her area. Critical questions needed answers: Had the man infected anyone else? Was the deadly virus already lurking in other communities and spreading?

As luck would have it, Dr. Chu had a way to monitor the region. For months, as part of a research project into the flu, she and a team of researchers had been collecting nasal swabs from residents experiencing symptoms throughout the Puget Sound region.

To repurpose the tests for monitoring the coronavirus, they would need the support of state and federal officials. But nearly everywhere Dr. Chu turned, officials repeatedly rejected the idea, interviews and emails show, even as weeks crawled by and outbreaks emerged in countries outside of China, where the virus began.

By Feb. 25, Dr. Chu and her colleagues could not bear to wait any longer. They began performing coronavirus tests, without government approval.

What came back confirmed their worst fear. They quickly had a positive test from a local teenager with no recent travel history. The coronavirus had already established itself on American soil without anybody realizing it.

“It must have been here this entire time,” Dr. Chu recalled thinking with dread. “It’s just everywhere already.”

In fact, officials would later discover through testing, the virus had already contributed to the deaths of two people, and it would go on to kill 20 more in the Seattle region over the following days.

Federal and state officials said the flu study could not be repurposed because it did not have explicit permission from research subjects; the labs were also not certified for clinical work. While acknowledging the ethical questions, Dr. Chu and others argued there should be more flexibility in an emergency during which so many lives could be lost. On Monday night, state regulators told them to stop testing altogether.

The failure to tap into the flu study, detailed here for the first time, was just one in a series of missed chances by the federal government to ensure more widespread testing during the early days of the outbreak, when containment would have been easier. Instead, local officials across the country were left to work in the dark as the crisis grew undetected and exponentially.

Even now, after weeks of mounting frustration toward federal agencies over flawed test kits and burdensome rules, states with growing cases such as New York and California are struggling to test widely for the coronavirus. The continued delays have made it impossible for officials to get a true picture of the scale of the growing outbreak, which has now spread to at least 36 states and Washington, D.C.

Dr. Robert R. Redfield, director of the Centers for Disease Control and Prevention, said in an interview on Friday that acting quickly was critical for combating an outbreak. “Time matters,” he said.

He insisted that despite the rocky start, there was still time to beat back the coronavirus in the United States. “It’s going to take rigorous, aggressive public health — what I like to say, block and tackle, block and tackle, block and tackle, block and tackle,” he said. “That means if you find a new case, you isolate it.”

But the Seattle Flu Study illustrates how existing regulations and red tape — sometimes designed to

protect privacy and health — have impeded the rapid rollout of testing nationally, while other countries ramped up much earlier and faster. Faced with a public health emergency on a scale potentially not seen in a century, the United States has not responded nimbly.

The C.D.C.'s own effort to create a system for monitoring the virus around the country, using established government surveillance networks for the flu, has not yet built steam. And as late as last week, after expanding authorizations for commercial and academic institutions to make tests, administration officials provided conflicting accounts of when a significant increase in tests would be available.

In states like Maine, Missouri and Michigan, where there are few or no known infections, state public health officials say they have more than enough tests to meet demand.

But it remains unclear how many Americans have been tested for the coronavirus. The C.D.C. says approximately 8,500 specimens or nose swabs have been taken since the beginning of the outbreak — a figure that is almost certainly larger than the number of people tested since one person can have multiple swabs. By comparison, South Korea, which discovered its first case around the same time as the United States, has reported having the capacity to test roughly 10,000 people a day since late February.

A prime mission

As soon as the genetic sequence of the coronavirus was published in January, the C.D.C.'s first job was to develop a diagnostic test. "That's our prime mission," Dr. Redfield said, "to get eyes on this thing."

The agency also released criteria for deciding which individuals should be tested for the virus — at first only those who had a fever and respiratory issues and had traveled from the outbreak's origin in Wuhan, China.

The criteria were so strict that the sick man in the Seattle area who had visited Wuhan did not meet it. Still, worried state health officials pushed to get him checked, and the C.D.C. agreed. Local officials sent a sample to Atlanta and the results came backpositive.

Officials monitored 70 people who were in contact with the man, including 50 who consented to getting nose swabs, and none tested positive for the coronavirus. But there was still the possibility that someone had been missed, said Dr. Scott Lindquist, the state epidemiologist for communicable diseases.

Around this time, the Washington State Department of Health began discussions with the Seattle Flu Study already going on in the state.

But there was a hitch: The flu project primarily used research laboratories, not clinical ones, and its coronavirus test was not approved by the Food and Drug Administration. And so the group was not certified to provide test results to anyone outside of their own investigators. They began discussions with state, C.D.C. and F.D.A. officials to figure out a solution, according to emails and interviews.

Dr. Scott F. Dowell, a former high-ranking C.D.C. official and a current deputy director at the Bill &

Melinda Gates Foundation, which funds the Seattle Flu Study, asked for help from the leaders of the C.D.C.'s coronavirus response. "Hoping there is a solution," he wrote on Feb. 10.

Later, Dr. Lindquist, the state epidemiologist in Washington, wrote an email to Dr. Alicia Fry, the chief of the C.D.C.'s epidemiology and prevention branch, requesting the study be used to test for the coronavirus.

C.D.C. officials repeatedly said it would not be possible. "If you want to use your test as a screening tool, you would have to check with F.D.A.," Gayle Langley, an officer at the C.D.C.'s National Center for Immunization and Respiratory Disease, wrote back in an email on Feb. 16. But the F.D.A. could not offer the approval because the lab was not certified as a clinical laboratory under regulations established by the Centers for Medicare & Medicaid Services, a process that could take months.

Dr. Chu and Dr. Lindquist tried repeatedly to wrangle approval to use the Seattle Flu Study. The answers were always no.

"We felt like we were sitting, waiting for the pandemic to emerge," Dr. Chu said. "We could help. We couldn't do anything."

Sense of exasperation

As Washington State debated with the federal officials over what to do, the C.D.C. confronted the daunting task of testing more widely for the coronavirus.

The C.D.C. had designed its own test as it typically does during an outbreak. Several other countries also developed their own tests.

But when the C.D.C. shipped test kits to public labs across the country, some local health officials began reporting that the test was producing invalid results.

The C.D.C. promised that replacement kits would be distributed within days, but the problem stretched on for over two weeks. Only five state laboratories were able to test in that period. Washington and New York were not among them.

By Feb. 24, as new cases of the virus began popping up in the United States, the state labs were growing frantic.

The Association of Public Health Laboratories made what it called an "extraordinary and rare request" of Dr. Stephen Hahn, the commissioner of the F.D.A., asking him to use his discretion to allow state and local public health laboratories to create their own tests for the virus.

"We are now many weeks into the response with still no diagnostic or surveillance test available outside of C.D.C. for the vast majority of our member laboratories," Scott Becker, the chief executive of the association, wrote in a letter to Dr. Hahn.

Dr. Hahn responded two days later, saying in a letter that “false diagnostic test results can lead to significant adverse public health consequences” and that the laboratories were welcome to submit their own tests for emergency authorization.

But the approval process for laboratory-developed tests was proving onerous. Private and university clinical laboratories, which typically have the latitude to develop their own tests, were frustrated about the speed of the F.D.A. as they prepared applications for emergency approvals from the agency for their coronavirus tests.

Dr. Alex Greninger, an assistant professor at the University of Washington Medical Center in Seattle, said he became exasperated in mid-February as he communicated with the F.D.A. over getting his application ready to begin testing. “This virus is faster than the F.D.A.,” he said, adding that at one point the agency required him to submit materials through the mail in addition to over email.

New tests typically require validation — running the test on known positive samples from a patient or a copy of the virus genome. The F.D.A.’s process called for five. Obtaining such samples has been hard because most hospital labs have not seen coronavirus cases yet, said Dr. Karen Kaul, chair of the department of pathology and laboratory medicine at NorthShore University HealthSystem in Illinois.

She said she had to scramble to obtain virus RNA from a laboratory in Europe. “Everyone is trying to figure out what we can get to help us gather the data that we need,” she said.

The F.D.A. has disputed that it moved too slowly, saying that it provided emergency authorization for two laboratory-developed tests within 24 hours of a completed submission — one was the C.D.C.’s test and the other a test developed by New York’s Wadsworth laboratory after it had trouble verifying the C.D.C.’s test.

‘What do we do?’

On the other side of the country in Seattle, Dr. Chu and her flu study colleagues, unwilling to wait any longer, decided to begin running samples.

A technician in the laboratory of Dr. Lea Starita who was testing samples soon got a hit.

“I’m like, ‘Oh my God,’” Dr. Starita said. “I just took off running” to the office of the study’s program managers. “We got one,” she told them. “What do we do?”

Members of the research group discussed the ethics of what to do next.

“What we were allowed to do was to keep it to ourselves,” Dr. Chu said. “But what we felt like we needed to do was to tell public health.”

They decided the right thing to do was to inform local health officials.

The case was a teenager, in the same county where the first coronavirus case had surfaced, who had a flu swab just a few days before but had no travel history and no link to any known case.

The state laboratory, finally able to begin testing, confirmed the result the next morning. The teenager, who had recovered from his illness, was located and informed just after he entered his school building. He was sent home and the school was later closed as a precaution.

Later that day, the investigators and Seattle health officials gathered with representatives of the C.D.C. and the F.D.A. to discuss what happened. The message from the federal government was blunt. “What they said on that phone call very clearly was cease and desist to Helen Chu,” Dr. Lindquist remembered. “Stop testing.”

A silent spread

Still, the troubling finding reshaped how officials understood the outbreak. Seattle Flu Study scientists quickly sequenced the genome of the virus, finding a genetic variation also present in the country’s first coronavirus case.

The implications were unnerving. There was a good chance that the virus had been circulating silently in the community for around six weeks, infecting potentially hundreds of people.

On a phone call the day after the C.D.C. and F.D.A. had told Dr. Chu to stop, officials relented, but only partially, the researchers recalled. They would allow the study’s laboratories to test cases and report the results only in future samples. They would need to use a new consent form that explicitly mentioned that results of the coronavirus tests might be shared with the local health department.

They were not to test the thousands of samples that had already been collected.

The same day, the F.D.A. said it would relax its rules and allowclinical labs to begin using their own coronavirus tests as long as they submitted evidence that they worked to the agency. Under that new policy, according to an agency representative on Tuesday, it had heard from 14 labs, with 10 already beginning patient testing.

On March 2, the Seattle Flu Study’s institutional review board at the University of Washington determined that it would be unethical for the researchers not to test and report the results in a public health emergency, Dr. Starita said. Since then, her laboratory has found and reported numerous additional cases, all of which have been confirmed.

As new samples came in, Dr. Starita’s laboratory also worked their way backward through some older samples that had been sitting in the freezers for weeks, finding cases that date back to at least Feb. 20 — seven days before public health officials had any idea the virus was in the community.

The scientists said they believe that they will find evidence that the virus was infecting people even earlier, and that they could have alerted authorities sooner if they had been allowed to test.

But on Monday night, state regulators, enforcing Medicare rules, stepped in and again told them to stop until they could finish getting certified as a clinical laboratory, a process that could take many weeks.

In the days since the teenager’s test, the Seattle region has spun into crisis, with dozens of people

testing positive and at least 22 dying — many of them infected in a nursing home that had unknowingly been suffering casualties since Feb. 19.

The availability of testing for coronavirus remains uneven, with some people able to easily obtain tests in certain parts of the country while others have been turned away. Some state officials fear that the virus is spreading far faster than the capacity for testing is increasing.

Looking back, Dr. Chu said she understood why the regulations that stymied the flu study's efforts for weeks existed. "Those protections are in place for a reason," she said. "You want to protect human subjects. You want to do things in an ethical way."

The frustration, she said, was how long it took to cut through red tape to try to save lives in an outbreak that had the potential to explode in Washington State and spread in many other regions. "I don't think people knew that back then," she said. "We know it now."

Reporting was contributed by Nicholas Bogel-Burroughs, Joseph Goldstein, Sheila Kaplan, Michael D. Shear, Knvul Sheikh, Katie Thomas and Noah Weiland.