# Have a Case of a COVID Variant? No One Is Going to Tell You

Lab officials say they can't tell patients or their doctors whether someone has been infected by a COVID variant.

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COVID-19 infections from variant strains are quickly spreading across the U.S., but there's one big problem: Lab officials say they can't tell patients or their doctors whether someone has been infected by a variant.

Federal rules around who can be told about the variant cases are so confusing that public health officials may merely know the county where a case has emerged but can't do the kind of investigation and deliver the notifications needed to slow the spread, according to Janet Hamilton, executive director of the Council of State and Territorial Epidemiologists.

"It could be associated with a person in a high-risk congregate setting or it might not be, but without patient information, we don't know what we don't know," Hamilton said. The group has asked federal officials to waive the rules. "Time is ticking."

The problem is that the tests in question for detecting variants have not been approved as a diagnostic tool either by the Food and Drug Administration or under federal rules governing university labs — meaning that the testing being used right now for genomic sequencing is being done as high-level lab research with no communication back to patients and their doctors.

Amid limited testing to identify different strains, more than 1,900 cases of three key variants have been detected in 46 states, according to the Centers for Disease Control and Prevention. That's worrisome because of early reports that some may spread faster, prove deadlier or potentially thwart existing treatments and vaccines.

Officials representing public health labs and epidemiologists have warned the federal government that limiting information about the variants — in accordance with arcane regulations governing clinical labs — could hamper efforts to investigate pressing questions about the variants.

The Association of Public Health Laboratories and the Council of State and Territorial Epidemiologists earlier this month jointly pressed federal officials to "urgently" relax certain rules that apply to clinical labs.

Washington state officials detected the first case of the variant discovered in South Africa this week, but the infected person didn't provide a good phone number and could not be contacted about the positive result. Even if health officials do track down the patient, "legally we can't" tell him or her about the variant because the test is not yet federally approved, Teresa McCallion, a spokesperson for the state department of health, said in an email.

"However, we are actively looking into what we can do," she said.

Lab testing experts describe the situation as a Catch-22: Scientists need enough case data to make sure their genome-sequencing tests, which are used to detect variants, are accurate. But while they wait for results to come in and undergo thorough reviews, variant cases are surging. The lag reminds some of the situation a year ago. Amid regulatory missteps, approval for a COVID-19 diagnostic test was delayed while the virus spread undetected.

The limitations also put lab professionals and epidemiologists in a bind as public health officials attempt to trace contacts of those infected with more contagious strains, said Scott Becker, CEO of the Association of Public Health Laboratories. "You want to be able to tell [patients] a variant was detected," he said.

Complying with the lab rules "is not feasible in the timeline that a rapidly evolving virus and responsive public health system requires," the organizations wrote.

Hamilton also said telling patients they have a novel strain could be another tool to encourage cooperation — which is waning — with efforts to trace and sample their contacts. She said notifications might also further encourage patients to take the advice to remain isolated seriously.

"Can our investigations be better if we can disclose that information to the patient?" she said. "I think the answer is yes."

Public health experts have predicted that the B117 variant, first found in the United Kingdom, could be the predominant variant strain of the coronavirus in the U.S. by March.

As of Tuesday, the CDC had identified nearly 1,900 cases of the B117 variant in 45 states; 46 cases of B1351, which was first identified in South Africa, in 14 states; and five cases of the P.1 variant initially detected in Brazil in four states, Rochelle Walensky, MD, MPH, the CDC director, told reporters Wednesday.

A Feb. 12 memo from North Carolina public health officials to clinicians stated that because genome sequencing at the CDC is done for surveillance purposes and is not an approved test under the Clinical Laboratory Improvement Amendments program — which is overseen by the U.S. Centers for Medicare & Medicaid Services — "results from sequencing will not be communicated back to the provider."

Earlier this week, the topic came up in Illinois as well. Notifying patients that they are positive for a COVIF variant is "not allowed currently" because the test is not CLIA-approved, said Judy Kauerauf,

section chief of the Illinois Department of Public Health communicable disease program, according to a record obtained by the Documenting COVID-19 project of Columbia University's Brown Institute for Media Innovation.

The CDC has scaled up its genomic sequencing in recent weeks, with Walensky saying the agency was conducting it on only 400 samples weekly when she began as director compared with more than 9,000 samples the week of Feb. 20.

The Biden administration has committed nearly $200 million to expand the federal government's genomic sequencing capacity in hopes it will be able to test 25,000 samples per week.

"We'll identify COVID variants sooner and better target our efforts to stop the spread. We're quickly infusing targeted resources here because the time is critical when it comes to these fast-moving variants," Carole Johnson, testing coordinator for President Joe Biden's COVID-19 response team, said on a call with reporters this month.

Hospitals get high-level information about whether a sample submitted for sequencing tested positive for a variant, said Nick Gilpin, DO, director of infection prevention at Beaumont Health in Michigan, where 210 cases of the B117 variant have been detected. Yet patients and their doctors will remain in the dark about who exactly was infected.

"It's relevant from a systems-based perspective," Gilpin said. "If we have a bunch of B117 in my backyard, that's going to make me think a little differently about how we do business."

It's the same in Washington state, McCallion said. Health officials may share general numbers, such as 14 out of 16 outbreak specimens at a facility were identified as B117 — but not who those 14 patients were.

There are arguments for and against notifying patients. On one hand, being infected with a variant won't affect patient care, public health officials and clinicians say. And individuals who test positive would still be advised to take the same precautions of isolation, mask-wearing and hand-washing regardless of which strain they carried.

"There wouldn't be any difference in medical treatment whether they have the variant," said Mark Pandori, director of the Nevada State Public Health Laboratory. However, he added that "in a public health emergency it's really important for doctors to know this information."

Pandori estimated there may be only 10 or 20 labs in the U.S. capable of validating their laboratory-based variant tests. One of them doing so is the lab at the University of Washington in Seattle.

Alex Greninger, MD, PhD, assistant director of the clinical virology laboratories there, who co-created one of the first tests to detect SARS-CoV-2, said his lab began work to validate the sequencing tests last fall.

Within the next few weeks, he said, he anticipates having a federally authorized test for whole-genome sequencing of COVID. “So all the issues you note on notifying patients and using [the] results will not be a problem,” he said in an email.

Companies including San Diego-based Illumina have approved COVID-testing machines that can also detect a variant. However, since the add-on sequencing capability wasn’t specifically approved by the FDA, the results can be shared with public health officials — but not patients and their doctors, said Phil Febbo, MD, Illumina’s chief medical officer.

He said they haven’t asked the FDA for further approval but could if variants start to pose greater concern, like escaping vaccine protection.

“I think right now there’s no need for individuals to know their strains,” he said.

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