Understanding the COVID-19 testing lag, and how we catch up

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Of the countless voices opining about the coronavirus, few have as much relevant expertise as George Horvath.

On the medical side, he was a practicing doctor for 15 years and a partner in the Berkeley Cardiovascular Medical Group. On the legal side, he is an authority on healthcare regulation who has taught related courses at Berkeley Law as a postdoctoral fellow and lecturer since 2015.

No wonder, then, that Horvath welcomed a large crowd of online visitors for his recent Zoom presentation about America's barriers to widespread testing in the pandemic's early stages.

Exploring the technical challenges, legal constructs, and policy choices that led to paltry testing, he said the lessons being learned now "inform a program for approaching the next pandemic, because one is going to come."

Horvath, who was editor-in-chief of the *California Law Review* as a student and a former clerk for U.S. Ninth Circuit Court of Appeals Judge John Noonan Jr., described how confusion surrounding federal agency oversight and misguided testing structures fueled the delays.

"Decisions were made before the crisis began," he said. "There was sparing use of the Defense Production Act for testing supplies. There's a strategic national stockpile of ventilators but also of testing materials like swabs, and those were assigned low priority and now aren't as robust as we'd like."

Trouble spots

Unpacking the multi-layered process from the initial ribonucleic acid (RNA) extraction through producing test results, Horvath noted a disturbing rate of false-positive tests and problems posed by the small number of test-kit manufacturers.

"It's an FDA-regulated product, so it's difficult for new manufacturers to

jump in and fill the void," he said, explaining the highly specialized nature of tools and machinery needed to isolate RNA. "There are a number of technical issues related to the complexity of the testing and shortages in some very basic supplies as worldwide demand has skyrocketed."

Pivoting to the legal and policy realm, Horvath discussed statutory and regulatory barriers to more widespread testing. While the Food, Drug, and Cosmetic Act gives the FDA authority over medical devices, the agency overlaps with the Centers for Medicare and Medicaid Services (CMS) in regulating labs where testing is done.

The Bioshield Act of 2004, enacted to counter a possible bioterrorist attack, provided a way to bypass standard FDA pre-market requirements and expedite the normal timetable for providing treatments in emergency situations. If the secretary of Health and Human Services determines that a public health emergency exists, the FDA may approve the use of otherwise non-approved products, provided the known and potential benefits outweigh the dangers for each product.

That power was invoked in the fight against the coronavirus, lowering threshold standards and letting companies use computer modeling to show their testing kits can work.

While this has permitted the Center for Disease Control and Prevention (CDC), academic labs, and others to develop tests and distribute them in the U.S., efficiency remains elusive. Case in point: The CMS divides labs into different categories in order to be certified, but "the FDA maintains it has oversight authority over all complex testing—though it previously said it would not regulate testing developed and used exclusively within the same lab," Horvath said.

Iffy implementation

He also detailed implementation decisions that slowed testing expansion in the U.S. For starters, the CDC created a test that was more complicated—looking for three stretches of RNA—than those in other nations that looked for two stretches.

"Why the CDC decided to go with a test of that complexity isn't clear. The most recent guidance has said it's permissible to look even for a single highly permissive stretch of RNA," Horvath explained, noting that "moving toward a more simplified testing scheme" would fuel efficiency.

Also, the CDC's early decision to establish restrictive criteria for who could be tested—those who traveled to an endemic area or who had been in contact with a person affected—conserved the limited number of tests. While the criteria has been loosened substantially, the lost time likely contributed to the virus' spread. Horvath also questioned the CDC's decision to allocate test kits equally across states regardless of their population.

Reliance on "a highly decentralized system of testing and a multipolar regulatory system proved problematic," he said, noting that "there's no one easily correctable cause as to why the U.S. has lagged behind so many countries in getting testing up and running."

Had CMS's oversight of clinical labs been the sole regulating framework, Horvath said, testing would have ramped up faster. "Where the FDA stepped in and exercised what it sees as its authority overseeing lab testing, that has created some of the bottleneck."

Looking ahead, he sees vaccine development facing more stringent regulatory obstacles because of "a higher need to ensure safety and effectiveness. It's one thing if your coronavirus test misfires and gives a false-positive versus safety issues from vaccinating a huge part of the

population."

Horvath's more immediate prescription? "We need to collect samples from vast numbers of people who are symptomatic as well as non-symptomatic to understand when it's safe to reopen the economy."

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