

The Daily Dish

The FDA and COVID Testing Priorities

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Eakinomics: The FDA and COVID Testing Priorities

This Week in Virology (TWiV) is a podcast on viruses – "the kind that make you sick," as they say – and, courtesy of my beloved wife Beth, I am now a fan. In particular, take a listen to episode 640 on COVID-19 testing. Here is what I learned, albeit with the terminology abused and the science skewered by my ignorance.

We have focused attention on the gold standard, clinical test (a "PCR – polymerase chain reaction" – test), which can detect the slightest presence of the virus. This test is too expensive to do wide-scale surveillance, however, and takes a *long* time. Instead, we could use a cheaper – literally \$1 – and faster test, be able to test much more broadly and frequently, and do just as well in preventing the spread of COVID-19.

How can this be?

The key is how the virus grows. Initially, it is undetectable. Once it hits a level that would detectable by a PCR test, however, it is growing exponentially and generating enormous amounts of RNA. Within a few hours it will be detectable with the lower-quality assay, even though symptoms are not yet present. As the body fights back, the levels of RNA decline. For what could be weeks – and in some cases even months – the virus would remain but only be detectable by the PCR test.

But who cares? As it turns out, there is only a window of a week or less during which the virus is transmissible, which coincides with the exponential growth. So, if it is important to catch people who can transmit the disease, it is important to catch it early on. For this purpose, it essentially does not matter which test you use. But because we are using the gold standard assay, testing is too slow and expensive to be done frequently and broadly enough to stop the disease.

As a specific example, a lot has been made of the fact that the Abbott ID Now test (an example of the lower-quality assay that was used by the White House) missed 50 percent of the cases that the PCR test caught. But people spend most of their time at the edge of PCR detectability in the latter stages of the disease, long after they are contagious. The 50 percent of cases that both tests catch are precisely the ones that need to be identified to stop the spread of the disease. The really bad-news part of this story is that the Food and Drug Administration has decided that all tests should catch at least 80 percent of the cases a PCR test would catch. This is keeping fast, cheap, lower-quality assays off the market.

We want a test everyone can take every morning. If it comes back positive, you stay home from school or work. We don't have it because the U.S. system is biased toward clinical testing when the public health imperative is surveillance testing, even though the economics of surveillance testing are far less daunting.