Can COVID-19 Testing Technologies Apply to Hepatitis C and Other Diseases?

Testing advances made during the COVID-19 pandemic may lead to “test and treat” approaches for hepatitis C. But there’s a holdup.

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What will be the next game-changing advancement in the treatment of hepatitis C? If Australia, France and the United Kingdom offer any indication, the arrival of automated molecular tests could boost hepatitis C treatment rates, according to the New York Times.

The United States lags behind those nations in part because Cepheid, a California-based company that developed the testing technology used abroad, has not submitted its hep C tests for approval in the United States.

Although hepatitis C virus can be cured with effective and relatively simply treatment—usually a regimen of daily tablets for several weeks—treatment rates are declining in the United States. This is partly due to the shutdowns and stay-at-home orders enforced during the COVID-19 pandemic as well as the fact that many researchers, clinics and health care workers prioritized tackling the coronavirus.

However, the decrease in hep C treatment rates contrasts with a spike in new cases, driven by the opioid crisis and occurring notably among people in their 20s and 30s who inject drugs, a common route of hepatitis C transmission (this is also a pathway for hepatitis B and HIV, but those two viruses are not curable).

Hepatitis C virus attacks the liver. In fact, hepatitis means “inflammation of the liver.” Left untreated, hepatitis can lead to cirrhosis (scarring of the liver), liver cancer, the need for a liver transplant and death. Like hepatitis B and HIV, hep C is usually transmitted by shared needles and sex (though hep B and HIV are not curable). For more, see Hep’s Basics on Hepatitis C.

It’s estimated that 2.4 million Americans were living with chronic hep C between 2013 and 2016 (about 1% of the adult population), according to the Centers for Disease Control and Prevention. What’s more, 14,242 people died of hepatitis C in 2019, and acute hep C cases quadrupled from 2009 to 2019.

A major hurdle to starting hep C treatment is the series of diagnostic tests folks must undergo to determine the best treatment regimen. This requires several trips to clinics, often spread out over weeks and even months, which may be difficult for people who can't take time off work or don't have transportation and near impossible for those experiencing addiction, homelessness or incarceration.

That's where new testing technologies come into play. To meet testing needs during the COVID-19 pandemic, the Food and Drug Administration (FDA) loosened its strict policies on the regulatory testing process, for example, while at the same time, at-home tests and telehealth became more commonplace.

"Perhaps one of the most enduring technological innovations [to result from the COVID-19 response] will be the advent of accurate diagnostic tests that can be used at home to provide a rapid answer about a person's clinical status," writes Scott Gottlieb, MD, the former head of the FDA, in a JAMA Forum in December. "This ability to connect at-home diagnostic tests with telemedicine and rapid turnaround of definitive laboratory testing will change infectious disease management. These systems will reduce office visits that can risk the spread of disease to others, make rapid assessment and treatment more possible, and expand access to timely, more affordable medical care."

How might his apply to hepatitis C treatment? As the Hep Basics section on Hepatitis C Testing spells out, the testing process is not so simple:

> Initial testing for hepatitis C has three parts. The first test, the HCV antibody test, sees if you have been exposed to the virus. The second test is the viral load test, and it detects whether you were merely exposed or if you actually have hep C. If that test is positive, then a genotype test is done to find out what kind of hep C you have.
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> Genotype refers to the genetic structure or makeup of living organisms. The hepatitis C virus has eight different genotypes, which are numbered in the order of their discovery. Each of these genotypes has subtypes, which were lettered in the order that they were discovered. It is important to find out which hepatitis C genotype you have, because it determines the best treatment for you.

As the New York Times notes, developing automated molecular tests that can be run on small machines the size of laptops would streamline the hep C testing process. Ideally, such technology would allow a "test and treat" approach to hepatitis C, meaning that a person who tests positive can start treatment right away.

Similar testing advances were made for the coronavirus and could lead the way in the hepatitis C field. At least one company—California-based Cepheid—has already developed diagnostic tests and the smaller machines, called GeneXpert, on which to run them. The portable size means that testing can be accomplished via mobile clinics.

Cepheid's hep C testing system was approved in Europe in 2018 and in Australia last year. But although the company had 5,000 GeneXpert machines in the United States as of March 2020, according to the Times, it has not submitted its diagnostic test to the FDA for approval. Instead, Cepheid has focused on COVID-19 testing, although a spokesperson told the Times that Cepheid is "assessing a path forward" regarding FDA approval for the hep C devices in the United States.

Researchers urge Cepheid, a subsidiary of Danaher, to begin the process, noting that Cepheid developed its breakthrough technology using grants, tax credits and government support.

"This is a whole class of technologies that could have a lot of potential for hepatitis C that are just completely stalled on the regulatory side," Annette Gaudino, director of policy strategy at the Treatment Action Group, told the Times.

In related news, a recent CDC program that mailed free HIV tests to 100,000 Americans did a better job of reaching people who'd never been tested. For more about that, read "Is It Time for Free HIV Self-Tests From the Government?"

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