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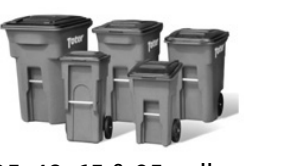
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outcomes of the disease. Each category, from education to income inequality, has its own tradeoffs.

COVID has many of the same tradeoffs, from the dangers of herd immunity to unanswered questions on what the actual death rate is. The biggest challenge, however, is that much of the current data being used to make informed decisions is flawed. “Testing was rolled out with nowhere near the amount of validation as it would have in the past,” said William Foster, PeaceHealth Peace Harbor’s emergency department medical director. “Even a lot of the scientific studies that are being put out are not being peer reviewed. They’re being released before that can happen.”

At the beginning of the outbreak, the sparse information that was known about the virus was grim: 14 percent death rate in Italy, 10 percent in Britain and France. Hospitals were being overloaded in communities of every size, and the disease was spreading rapidly.

Information was needed as quickly as possible, but the peer review process takes time, anywhere from a few months to years to complete. Many studies began giving out preliminary results during the peer review process.

“From a scientific viewpoint, we’re trying to get the information out there,” Foster said. “Is it good information? Well, no. This doesn’t really have the standards to be published. Now those papers are getting out there. Some of it’s going to be proven accurate, and some of it is going to be proven not to be as time goes on.”

One of the most heated debates over the accuracy of studies involves COVID-19 antibodies, with questions on both their efficacy and how they’re tested.

All of those questions are unanswered

On Monday, the Food and Drug Administration (FDA) issued an ultimatum to all companies manufacturing antibody tests for COVID: Produce evidence

that the test works or it will be pulled from shelves.

“In mid-March, it was critical for the FDA to provide regulatory flexibility for serology test developers, given the nature of this public health emergency and an understanding that the

“Because this disease is so new, we don’t know how long it lasts. Measles is for a lifetime. The flu changes every year. This virus is in the coronavirus family, which causes common colds. You can get multiple colds a year. We don’t really know how this virus is going to act.”

— William Foster, Emergency Department Medical Director at PeaceHealth Peace Harbor

tests were not to be used as the sole basis for COVID-19 diagnosis — a fact that remains true today,” the FDA wrote. “However, flexibility never meant we would allow fraud.”

The FDA found “unscrupulous actors” marketing fraudulent test kits, while other serology tests had false positives only 14 percent of the time.

“From my understanding, it’s even less regulated than the rapid testing for the actual virus,” Foster said.

Some of these tests were used in some rather influential studies released in the past two months. A study in Santa Clara County found that between 48,000 and 82,000 people had antibodies, compared to just 1,000 “confirmed” cases. The death rate was between 0.12 and 0.2 percent, slightly higher than influenza’s estimate of 0.1 percent.

New York City released an antibody study that suggested 1-in-5 residents already had the virus, representing a death rate of between 0.5 and 1 percent. This is compared to the 8 percent death rate the city has confirmed.

Those opposed to mandated statewide restrictions held up Santa Clara’s numbers as evidence that the shutdowns were an overreaction. But shortly after its release, the Santa Clara study was criticized for its lack of validity in the test kits used, and for recruiting applicants off of Facebook.

New York’s recruitment was also questioned, as the study pulled participants from grocery store shoppers who were more likely to

have contracted the disease over those following strict quarantine.

And, as New York pointed out, the number of dead used in the calculation for the death rate is also incorrect; New York only counted those who died while

in hospitals and nursing homes, not at home. Also excluded are patients who died of COVID but were misdiagnosed with influenza or pneumonia.

The drive behind the rigorous debate comes in part from the theory that antibodies will give a person a certain amount of immunity to COVID. But Foster states there’s no current evidence showing that is guaranteed.

“Can you get it a second time? Probably,” Foster said. “Because this disease is so new, we don’t know how long it lasts. Measles is for a lifetime. The flu changes every year. This virus is in the coronavirus family, which causes common colds. You can get multiple colds a year. We don’t really know how this virus is going to act.”

However, Foster does believe people will develop some form of immunity — “But how much and how long, we don’t know for sure,” he said. “There’s studies where some people have had pretty strong antibody responses, and some didn’t. We haven’t had enough time to know if immunity will last. It’s only been three months. All of those questions are unanswered at this point.”

The strength of antibodies leads to questions regarding the efficacy of a vaccine, which can take up to 18 months to be ready.

“There’s two sides to any vaccine,” Foster said. “You want to make sure that it doesn’t cause some unwanted effect. The other thing is, you want it to be effective and work. And that takes time to do that kind of testing.”

When a vaccine is finally developed, it is still unknown how long it will last.

“Is it a one time like for the measles, where you just need a couple of shots to develop a lifetime immunity?” Foster asked. “Are you going to have to get a vaccine every year, like the flu shot? We just don’t know that answer yet.”

Wouldn’t it just be better to let it go through the community...?

While answers are still being sought on a vaccine, some progress is being made on the over 700 treatments for COVID that are currently being tested.

“There’s so many different things being tried,” Foster said. “Some studies show they work, some raise questions. And then there’s always side effects to these medications as well.”

One of the most promising is Remdesivir, which Dr. Anthony Fauci, director

of the National Institute of Allergy and Infectious Diseases (NIAID), spoke with some optimism about last week.

A never-before-produced antiviral drug that was developed to treat the Ebola virus, Remdesivir has been involved with a number of clinical trials for COVID-19. While the study has not been peer reviewed, initial reports support the drug’s effectiveness in mitigating the illness in some patients.

But it is not a cure. Remdesivir works best if taken early in the disease, as it targets COVID’s replication mechanism, not killing the virus outright but preventing its growth. Initial studies have reported a marked decline in death rates — 11 percent dead with placebo compared to 8 percent dead with the Remdesivir. And the duration of recovery also declined, from 15 days to 11.

“Although a 31 percent improvement does not seem like a knockout 100 percent, it is a very important proof of concept because it has proven that a drug can block this virus,” Fauci said last week. “The real promise of the drug was what other treatments it could lead to.”

Though there are numerous other drugs and treatments being tested, including the anti-malaria drug hydroxychloroquine that was already on the market. While there have been reports of people hoarding the drug, “There seems to be a number of heart issues with it,” Foster said.

Some of the most recent studies have shown not as much benefit as preliminary ones did. Still, Foster does not blame people for trying the drug.

“I think if somebody was really sick in an ICU, and they don’t have any underlying heart issues, I’m going to try this,” Foster said. “Because we don’t have evidence that says it does work, but we don’t have hard evidence that says it doesn’t work. You’re kind of gambling, a little bit, because you don’t have time to do the studies.”

One other treatment talked about for COVID has been plasma donations, where a fully recovered patient can donate antibody-rich plasma to a patient without antibodies. Organizations such as the Red Cross are actively seeking recovered donors.

“One plasma donor, I think, can help three patients. It’s not like you can take the plasma from one patient and it treats thousands,” Foster said. “Even if you had COVID, how good is your plasma? Some people have had a very strong antibody response, others have had less. Not everyone who has had COVID is an ideal plasma donor.”

The lack of progress on a treatment and the uncertainty of a vaccine have led many people to ask whether or not communities should aim for herd immunity, where 70 to 90 percent of a population has a disease. If everyone is going to get the disease, why destroy the economy and put lives and livelihoods at risk?

See SAFETY page 6A



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