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Emergence of a Novel Coronavirus Disease (COVID-19) and the Importance of Diagnostic Testing: Why Partnership between Clinical Laboratories, Public Health Agencies, and Industry Is Essential to Control the Outbreak

Article:
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Guest: Dr. Matt Binnicker is the Director of Clinical Virology and Vice Chair of Practice in the Department of Laboratory Medicine and Pathology at Mayo Clinic.

Bob Barrett: This is a podcast from *Clinical Chemistry,* sponsored by the Department of Laboratory Medicine at Boston Children's Hospital. I am Bob Barrett.

In December 2019, a cluster of atypical pneumonia patients was detected in Wuhan, China. A novel betacoronavirus named as 2019 novel coronavirus, or COVID-19, was identified in these patients and now, two months later at the end of February 2020, the World Health Organization is on the verge of declaring this a worldwide pandemic. An Opinion piece on the importance of diagnostic testing and the partnership between clinical laboratories, public health, and the IVD industry being essential to control this outbreak is now online and will appear in the May 2020 issue of *Clinical Chemistry*. Its author, Dr. Matt Binnicker, is the Director of Clinical Virology and Vice Chair of Practice in the Department of Laboratory Medicine and Pathology at Mayo Clinic. His research interests focus on the development of rapid molecular diagnostics for viral infections, including transplant-associated viruses and emerging infectious diseases. So, Dr. Binnicker, can you share a brief update on the coronavirus outbreak and whether there are any signs that it's slowing down?

Dr. Matt Binnicker: Yeah, so the outbreak continues to evolve, really on a daily basis. More cases continue to be identified. The WHO, or World Health Organization, has officially named the illness as "coronavirus disease 2019," or you might hear COVID-19 for short. And the virus that's causing that disease has also been named and it's been given the name SARS-CoV-2 and that's because it's related to the original SARS virus that caused the outbreak of severe respiratory disease back in 2003. So, to date, there have been about 80,000 confirmed cases of COVID-19 and about 2,700 people have died from the infection. So, that's about a three percent mortality rate, which in comparison to the other SARS outbreak in 2003 and the Middle East respiratory syndrome coronavirus outbreak in 2012, those two outbreaks had a 10 percent and 35 percent mortality rate.

So, this is a lower percentage of people with COVID-19 who are dying, but there are a lot more confirmed cases of this

coronavirus disease compared to SARS and MERS. But when I look at the epidemiologic curves, and so that's the number of cases that are being identified and confirmed by the WHO every day, it seems like there's a leveling off of the reported cases, but we're still seeing more cases being identified every day. So, the strict quarantine practices that are being put in place will hopefully be successful in controlling the outbreak and reducing further spread of the disease, but we're really going to have to see how this plays out over the course of the next days and weeks.

Bob Barrett: Our listeners may have heard that coronaviruses can also cause the common cold. How is this virus different and what should physicians be looking for?

Dr. Matt Binnicker: Yeah, you're right. There are four other types of coronaviruses that are common and usually cause what we call the common cold—very minor respiratory symptoms: runny nose, cough, generally feeling unwell—and those circulate in the human population and don't typically cause major problems. But this current outbreak which is caused by the SARS-CoV-2 virus, which again causes that COVID-19 disease, is different. It's different because it has the potential to cause more serious respiratory disease including pneumonia and respiratory distress, so shortness of breath, difficulty breathing. And as I mentioned earlier, about three percent of people who are infected with this new type of coronavirus, SARS-CoV-2, have actually died from the infection.

And so that's not a typical outcome when people are infected with the more common types of coronaviruses that usually cause the common cold. So, I think it's really important that we are vigilant about controlling the outbreak because of the potential for a more severe disease in those that get infected. With regards to your question of what should physicians be looking for, at this point, the vast majority of cases—about 97 percent of all cases—have occurred in China. So what we're recommending is that physicians ask patients who they're seeing that are presenting with fever and respiratory symptoms like a cough, whether they've been to China in the past 14 days or if they've been in contact with someone who's been in China or they've been in contact with someone who's been confirmed to have COVID-19. And if the answer to those questions is "yes," then the physician should consider that patient what's called a patient under investigation, or PUI, for COVID-19.

Bob Barrett: Well, if a physician finds a patient that meets that criteria, is there a lab test that can be used to make the diagnosis?

Dr. Matt Binnicker: Yes, the good news is that there is a test, the bad news is that that test is not yet widely available. Currently, the U.S. Centers for Disease Control and Prevention, or the CDC, has developed a test to detect SARS-CoV-2 and the CDC has received what's called an Emergency Use Authorization, or EUA, from the United States Food and Drug Administration to perform that test. So, right now, all the testing for this new coronavirus is being sent to either the CDC or there's a small select few number of public health labs that have also been able to perform that test.

Bob Barrett: When do you think testing will be available at hospitals or clinical labs as well?

Dr. Matt Binnicker: So as of today, the CDC assay is not available for testing at local hospital and clinical labs. And if those labs want to be able to offer testing for this virus, they need to develop their own tests and then submit all their, what's called validation data, basically showing that the test works. They have to submit that data to the FDA, who will then review that data and then decide whether or not to issue an Emergency Use Authorization, or EUA, for that clinical lab to be able to perform the test. So, that's a very laborious, time-consuming process, so it's going to be really difficult for most clinical labs to accomplish that. But as the outbreak continues to evolve and especially if we see more and more cases here in the United States, the need for testing at local hospital clinical labs is going to increase. I think that there's the possibility that CDC will take a look at the approach and consider allowing select clinical labs to perform the testing that they've developed. But right now, as I mentioned earlier, that's not an option, I think it's a gap that we need to address.

Bob Barrett: Well finally, Dr. Binnicker, what do you think is needed to bring this global coronavirus outbreak under control?

Dr. Matt Binnicker: It's a very important question and I think it's going to take a team effort. These are really challenging situations. From the experience that we had with SARS and MERS, a key to controlling outbreaks like this is excellent infection control practices. In other words, what that means is that when suspect cases are identified, hospitals and healthcare providers need to have processes in place to identify suspect patients, to manage them, put them in certain rooms in hospitals or clinics, have certain approaches to collecting samples from them in order to prevent further spread of the virus to others. And an important component is also making sure those patients are away from other individuals, so that we can prevent spread of disease to other people.

I think we also need to make testing for the virus more broadly available, as I mentioned earlier, to hospital and

clinical labs, because that's actually where patients are being seen by healthcare providers. The challenge is that these patients are oftentimes presenting to their physician with non-specific symptoms. So, there's nothing that stands out about this new coronavirus in terms of the way people present to their physician that makes them stand out and say, "Yes, this patient definitely has this new coronavirus." They present with things like a fever and cough and other common respiratory infections like influenza, which is also circulating at high numbers in the population, can cause that.

Once a person is considered a "Patient Under Investigation," or PUI, for this COVID-19, hospitals and clinical labs often are changing their routine practices to keep healthcare staff and lab staff safe. So, they may not perform all of the normal procedures that they would typically do to manage a patient and labs may change the way that they do their testing approach because some processes and procedures might be unsafe. Because of that, a patient may not have a normal workup, and that can potentially negatively impact how they're managed and their outcome. So, by having a rapid answer to the question, "Does this patient have this SARS-CoV-2 or not?" we can change how we manage patients and hopefully get them the care that they need. So, to get that testing to the frontlines, that's actually at the hospital and clinical labs, I think we need to have a strong partnership between public health labs, clinical labs, companies such as device manufacturers, so that when these types of outbreaks occur, we can rapidly develop diagnostic tests and then get those tests to both the public health labs and clinical labs, so that patients can be accurately diagnosed in a timely fashion. And by timely, I mean we need to have answers to the physicians the day that they're seeing the patient and not several days later or a week later. And to get to that is going to require a lot of hard work, a lot of teamwork, but it's definitely something that we need to do.

Bob Barrett: That was Dr. Matt Binnicker, Director of Clinical Virology and Vice Chair of Practice in the Department of Laboratory Medicine and Pathology at Mayo Clinic. His Opinion piece on the importance of diagnostic testing and the partnership between clinical laboratories, public health, and the IVD industry being essential to control the 2019 novel coronavirus outbreak is online now and will appear in the May 2020 issue of *Clinical Chemistry*. I'm Bob Barrett. Thanks for listening.