# The Rapidly Changing COVID-19 Testing Landscape - Vaccines, Variants, and Health Disparities

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**Julie McDowell:**

The CAP recently hosted a virtual media briefing entitled, The Rapidly Changing COVID-19 Testing Landscape, Vaccines, Variants, and Health Disparities. More than a year into the pandemic, leading pathologists discuss the challenges of managing the impact of COVID-19 on multiple public health fronts, including health disparities in which preventable differences in the burden of disease are experienced by socially disadvantaged populations according to the CDC. This CAPcast episode features the audio recording of the briefing, which was moderated by Dr. Kisha Mitchell Richards; feature panelists included CAP President, Dr. Patrick Godbey, CAP Governor, Dr. Kalisha Hill, and Dr. Carey August, who is president of the CAP Foundation.

**Dr. Patrick Godbey:**

Hello and thank you for joining us today. My name is Dr. Patrick Godbey. I'm honored to serve as the president of the College of American Pathologists. The CAP represents about 18,000 board certified pathologists in the United States and around the world. The CAP is also the accrediting body for almost 8,000 laboratories worldwide. Pathologists and the laboratories we direct continue to be on the front lines of this pandemic, alongside our laboratory scientists and other physicians.

This is our first media briefing for 2021. The CAP is committed to providing members of the media with the most up-to-date information when it comes to testing for COVID-19, as well as other viruses and diseases. Before we begin, I would like to share some interesting survey results having to do with testing.

The CAP and Ipsos Digital, a global marketing company, put a survey into the field at the end of last year. 2,000 adults from the United States participated. Nearly two-thirds of those surveyed believe that getting regular medical laboratory tests is important to staying healthy. That belief falls to the bottom of the list behind managing mental health, eating healthy, getting an annual physical and 30 minutes of daily exercise. Those taking a COVID-19 test increased from 24 to 42% since our last online survey in August of 2020. Despite the constant COVID-19 news coverage and information being released, people are still having trouble understanding the tests that are available. This may be due to the shift in attention to the vaccine and/or being overwhelmed and confused by the amount of information available.

Finally, nearly two in three Americans would like more information about the accuracy of COVID-19 tests and how they are validated. Now, I'd like to turn things over to our moderator for today's discussion, Dr. Kisha Mitchell Richards.

**Dr. Kisha Mitchell Richards:**

Thank you, Dr. Godbey. My name is Dr. Kisha Mitchell Richards, and I am the director of Pathology and the Clinical Laboratory at Greenwich Hospital in Greenwich, Connecticut. I'd like to welcome our other panelists today, Dr. Kalisha Hill, and I'd like to ask Dr. Hill, could you please tell us a little bit about yourself?

**Dr. Kalisha Hill:**

Pleasure, and thank you for having me. I am Dr. Kalisha Hill. I am the regional chief medical officer for St. Mary's Hospital in Kankakee and Saint Joseph Medical Center in Joliet. I am also the laboratory medical director for St. Mary's Hospital in Kankakee, and I'm a proud governor for the College of American Pathologists.

**Dr. Kisha Mitchell Richards:**

Thank you, Dr. Hill. A pleasure to have you. Completing our panel today of pathologists is Dr. Carey August. Dr. August, can you introduce yourself for us?

**Dr. Carey August:**

Thank you. My name is Dr. Carey August. I am medical director of laboratories and department chair of pathology at Advocate Illinois Masonic Medical Center in Chicago. I am also very proud and honored to serve as the president of the College of American Pathologists Foundation, which is the charitable arm of the CAP.

**Dr. Kisha Mitchell Richards:**

Thank you, Dr. August. Such a pleasure to be here with my colleagues today. And it's a very, very significant day. It's one year ago today that the World Health Organization declared COVID-19 a pandemic and basically set in stone a year that was going to change our lives probably forever. What we know is our laboratories stepped up, they began to get to work, and over the last year, really worked very hard to handle what no one really had been very prepared for, and I'm extremely proud to be a member of that fraternity.

So as we get into our program today, we're all going to talk a little bit about the highs and lows, and I'd like you to share with me some of your highs and lows. And just to kick things off, I'm going to say that one of our highs, one of our most exhilarating moments here at Greenwich Hospital was on March 9th, 2020. We opened the first drive-through hospital testing site in Connecticut, and it was such a tremendous pleasure and honor to be able to deliver for patients laboratory testing at a time when people were very uncertain and unsure of how they would get testing.

One of the associated lows with that was that after we began to collect, some of the laboratories who had said they would take our tests were no longer able to, and we really had to scramble but again, pathologists came through and we had remarkable colleagues at the University of Washington that delivered for us and they were able to do our testing as we started. So we had highs and lows on the same day, almost a year to the day today.

So Dr. Godbey, can you tell me what were the highs when it came to how pathologists and our member laboratories handled the pandemic?

**Dr. Patrick Godbey:**

There were several, but one real high for the team that I was so honored to lead was being able to turn on a dime and change everything we did in the lab to meet the demands of COVID-19, a virus that we hadn't seen before. We had tremendous demands, a large number of patients and our medical laboratory scientists and our pathologists bet the challenge. I'm proud of our local lab, and I'm very proud of the members of the CAP and the medical labs that they direct, seeing how fast and how quickly they met the challenge. That's my high.

My low is not being able to deliver enough tests and enough accurate results quick enough. I'm glad to see the progress that we have made, but it was a real low, not being able to do it as quickly as we would have liked to. Thank you.

**Dr. Kisha Mitchell Richards:**

You're welcome. Thank you so much for sharing that. Dr. Hill, what stands out for you in terms of the highs and lows?

**Dr. Kalisha Hill:**

Yes. For me, the high clearly was the response of our laboratories to this pandemic. Within weeks in the month of March last year, our hospital was able to bring online testing within the hospital to screen patients for COVID, as well as our laboratory that is located in Hammond, Indiana, which is our core laboratory, Alverno, and they were able to bring up multiple platforms for real-time PCR in a very short period of time so that we can test the people in our community.

AMITA Health has worked tirelessly through all of the hospitals to make sure that we are providing access to our communities for testing and giving them the care that they need. So my greatest high is that collaboration between pathologists all over the country trying to determine what testing needed to be brought in-house and what testing needed to be referenced until testing could be brought in-house and how that collaboration really ramped up testing very quickly.

And we also noticed that during the several surges that we had last year across the country, it was very difficult to increase the response time so that we could still care for patients. So you had to test not only the people in the community, but also those needing preoperative testing. And sometimes, when we had a surge such as we did at AMITA St. Mary's Hospital in Kankakee in November, we had such a surge that what was taking a day or two to have the PCR results come back was now taking several days but we were able to respond very quickly. Our core laboratory was able to bring up additional analyzers and brought that turnaround time down relatively quickly. So we were very proud to continue to care for patients during that second surge.

So that being said, that does bring me to the low, and the low was those times when we had to close our operating rooms to allow us to care for our COVID patients and make sure we had processes in place to make the hospitals safe for people coming in for elective surgeries. And we were able to do that within a few weeks and open our ORs again and be able to welcome patients back to get the care that they need. But unfortunately, there were several patients, including one I remember as a pathologist, that had a two-centimeter tumor of the kidney that was to be resected but the surgery was canceled due to COVID and the patient had some reticence to come back to the hospital to get that surgery. And by the time the patient actually had the kidney removed, it had grown to eight centimeters.

So that delay in care was clear and glaring in my mind about how many people did not come to the hospital during the surges that we had, and many people were passing away at home because they tried to ride out the symptoms that they had. So those were the lows that I had, but I am grateful that we are moving forward and now have processes in place at all of our hospitals to care for both our COVID patients and our patients coming in for their care.

**Dr. Kisha Mitchell Richards:**

Thank you for sharing that. That story about patient reticence we will touch on a little bit later as we get into more of the discussion. And at the moment, I'm going to ask Dr. August, same question to you, tell me about your highs and lows.

**Dr. Carey August:**

Like all of my colleagues, I think the high for me was seeing how quickly our central laboratory, ACL Laboratories, could develop and implement COVID testing. It was just miraculous to see, and I'm very proud of that, and how the laboratory was able to add additional enhancements to make testing more available such as implementation of pooled testing, etc. So that was absolutely a high. I don't think most people can understand how much work goes into developing and validating tests, and this took place very quickly.

For me, the low was a little bit different. There was one day at the beginning of the pandemic when I felt this enormous responsibility not only for the functioning of our department but for the safety of everyone who works in our department and their families. I was struck by the enormity of what we were facing, and this led to another high. The cooperation our department had with other departments of the hospital to make sure we were all working safely and watching out for each other turned what should have been a major low into a major high. And it was great to see, and this interaction and cooperation at our hospital has carried on through the pandemic. It was there before, but I think it's going to be something very special going forward now.

**Dr. Kisha Mitchell Richards:**

Thank you so much for sharing that. I agree with you. I think it's likely we could all say we saw an element of that, and that is so rewarding as a clinician and as a pathologist to be able to be a part of that.

So today, what we're going to cover, we're going to try to be ambitious and get to a few topics, we're going to talk about the current state of testing. We're then going to talk about health disparities in the US, some of the unintended consequences of deferred care, which we've touched on a little bit, and then what the CAP is doing. And in particular, we are going to tell you about a tremendous program that the CAP has, the CAP Foundation's See, Test & Treat Program, which is one of the ways the CAP is working to help close some of the health disparities gap.

So to start our conversation today, we're going to begin with a discussion on some of the new at-home tests that have come to market and have received emergency use authorization or as we now are very familiar with, EUA. So Dr. Hill, can I ask you to tell us some of the important things you think that patients and people need to keep in mind when they're utilizing these new at-home tests?

**Dr. Kalisha Hill:**

Yes. We do understand the desire to have platforms outside of the hospital for testing in various environments. And while at-home testing will allow people to test themselves in their own home and environment, there are several items that we need to just address and make sure that everyone has understanding.

The gold standard is still a laboratory performed real-time PCR test, and that is the most sensitive and most accurate test that we do that is very specific for COVID-19. The tests that are done at home are good screening tools for people at a one-time basis, and so it's very important that people understand that when you're testing yourself for the moment, that does not mean that you're negative for a period of time. You are testing that moment that day, and as soon as you leave your home or come in contact with someone else, you could potentially be COVID-positive.

It's also important to recognize that when you're collecting a sample yourself, you may not be able to obtain enough sample for an accurate result. The laboratory technicians and staff that are working in many of our hospital settings, collecting nasal swabs, nasopharyngeal swabs, in some cases, saliva testing, they are trained and they do this pretty much multiple times a day so they have vast experience in knowing how much material to collect to make sure there's adequate sample to detect the virus. So it's very important how it's collected and also, the sensitivity and specificity of the test. The most important thing to recognize is that if you do have symptoms and are suspicious that you have COVID, it's very important to see your healthcare provider and obtain a real-time PCR test for confirmation.

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**Dr. Kisha Mitchell Richards:**

Thank you very much. I think as you get into the fact that these patients are doing these tests at home, some of these tests may need to be done multiple times for many reasons, sometimes even just because of the result of that at-home test. So on a purely practical level, cost can also become an issue. Some of these tests, unlike the hospital based or other more commercial laboratory tests, may not be covered by insurance, and so you may have to do self-claiming, that sort of thing. So it's important to bear that in mind as well that at some point, the cost may become an issue. The convenience is certainly a good factor, but sometimes we have to think about the overall picture of we're going for a COVID test.

So with that in mind, Dr. August, Dr. Hill touched on collection, can you elaborate on why it's so important for patients to collect an accurate sample when they're taking these tests?

**Dr. Carey August:**

As pathologists, we are laboratory professionals and we are imbued with the idea that every step in testing must be just right. There are so many things that can happen along the way. Sometimes people refer to pathologists as being a little persnickety about sample collection and sample preservation, but there's a reason for that, and it's the health of the people we serve. So if you've ever had a COVID test, the kind where they put the swab way, way up your nose, it's not comfortable, and people have to know that if they're going to do that particular test at home, they're going to have to do that to themselves. Fortunately, as other samples exist, such as saliva or the mid-turbinate collection, it may be less unpleasant for people, but it's so important to get the right specimen. This is part of the pre-analytic phase of testing.

Beyond that, if it is a test, for example, that you actually send to a laboratory for the final testing, you have to be sure. Is it all labeled properly? Is it preserved properly? Did you put it on the heater? Did it sit in the sun? All of these steps can contribute to false negatives, which is what we really do not want. So like the testing we do in the hospital and in our laboratories, we have to make sure that the public doing this at home understands the importance of proper collection and proper storage until it can be processed if it's being sent to another lab. It's critical.

**Dr. Kisha Mitchell Richards:**

Absolutely. As we can tell everyone the secret phrase, we sometimes use garbage in, garbage out. So with that in mind, Dr. Godbey, can you tell us some of the limitations of these at-home tests?

**Dr. Patrick Godbey:**

Certainly, and many of them have already been touched on. First, it's the collection of the sample. As you just said, garbage in, garbage out. If the sample is not good, you'll have an erroneous result. Most often, a false negative, and people will have false confident in that I'm negative when you may not be.

And when we talk about in-home tests, there are actually two different methods referred to as in-home tests. One is when the collection is done at home but you send that off to a lab. Remember, for most of those tests, you not only have to have the good collection but you have to get it off that day. Now for the tests that are both collected and performed at home, technique is extremely important. In our labs, medical laboratory scientists and pathologists, who are trained to do this can reproduce their testing capabilities. I worry about the technique that may be used in at-home testing.

And another problem is many of the tests that are performed at home rely on smartphones or computers to report the results. This may be a problem in vulnerable populations.

**Dr. Kisha Mitchell Richards:**

Access. Access to testing is such an important topic, and that false confidence issue may be even more relevant as we get into the new hot topic, which is the COVID-19 variants. I know many people are concerned about these variants and could these variants impact testing in the laboratory? The advent of these variants can have wide-reaching implications in terms of, one, we don't know about the infectivity of some of these variants, but I know the concern that exists in terms of testing relates to can our test pick up these variants?

And what I can say is in our experience, the commercially available test that we have that we are performing in our hospitals, in our accredited laboratories, so far, the variants that we are aware of and have detected are being picked up by these tests. So it's important to keep tracking them, and I know that many of our organizations are doing that. There's a lot of data on the CDC website. There is a beautiful map that can tell you where these variants are located. And I know that it's foremost on everyone's mind. So I would just ask my panelists to share their perspective on that. Dr. Hill, can you speak to this?

**Dr. Kalisha Hill:**

Yes. The variants have been very concerning. Soon after we had the surge in November, we were anticipating to turn a corner with the vaccines coming, everyone was exhausted. We were just looking for that light at the end of the tunnel, and then the variants started coming to the US. And so the heightened level of concern for our hospitals and for our patients and our community was palpable. So the first question that you mentioned in terms of these COVID tests that we have now brought up, we have ample testing as our community needs them and as our patients need them, will they detect these variants?

And similar to your laboratory, we immediately reached out to the manufacturer. They did their validation studies and did confirm that every single platform that we have brought to bear in all of our hospitals are able to detect every variant that has been identified thus far. And as new variants are detected, we will continue to make sure that they are validating that those testing platforms will detect those variants.

There's a huge question about how these variants impact patients, and the biggest concern is the severity of illness. And so it's very important that people recognize that the variants are being detected. And if you have symptoms, get tested with a real-time PCR test as soon as possible so that you can be treated earlier just in case you do have a variant that may make you sicker than the original virus strain.

**Dr. Kisha Mitchell Richards:**

So the cornerstone of tracking, diagnosing, tracking, treating during this pandemic has been testing. And even now as we go into that new realm of the variants, the variants, what do we do about variants? We still have to test. So an important issue is that laboratories have to have testing supplies, and we can all attest to how challenging that was at various stages of the pandemic. And Dr. Godbey, the CAP recently surveyed its member laboratories. What did they say about supplies? Are they still a problem?

**Dr. Patrick Godbey:**

Yes, we did survey them. We asked our member laboratories in the last three months, how difficult has it been for your laboratory to acquire each of the following items specific for COVID-19 testing? While the numbers went down, almost half the laboratories surveyed last month are still having problems securing reagents and test kits. 30% of the laboratories are showing shortages of pipette tips. The number of laboratories still short on SARS-CoV-2 instruments and nasopharyngeal swabs still hovers around 20%, but those numbers are way down from 43 and 60% respectively.

**Dr. Kisha Mitchell Richards:**

As you relate that information, I remember occasions my immunology manager would knock on the door open and she would just say, "The tips, the tips," and my heart would just sink because basically that meant we had to spend a whole day regrouping. So it's very, very real and relevant. So Dr. Godbey, tell us then, how does the CAP feel about the current administration's proposed allocation of money for these much needed lab supplies?

**Dr. Patrick Godbey:**

Well, to build on what you said earlier about the tips, labs in their very adaptive and innovative ways found some other ways to cope with the tips. One thing that we did is those same tips are required to perform testing for sexually transmitted diseases, so we stopped doing those tests in-house. Did that jeopardize patient care? Somewhat. But because of the lack of availability of consumables, including tips, we had to make compromises. Now the CAP continues to monitor this situation and applauds the Biden administration for earmarking fund for increasing testing supplies. After all, the basis of COVID-19 care is do you have COVID-19 or not? And it's a laboratory test that determines that.

**Dr. Kisha Mitchell Richards:**

But that anecdote about the testing, shifting testing from one area to another just illustrates it's an excellent point that tells us how the pandemic has affected day-to-day operations, and it's in so many ways that people don't realize in hospitals and laboratories across the country, we've really had to make some shifts. So Dr. August, can you tell us, share with me what you've seen, especially in your hospital?

**Dr. Carey August:**

I can think of two issues in particular. In November when we had a surge and our hospital's COVID inpatient population expanded again, we had to have once again an area for the COVID patients. So the number of phlebotomists or blood drawers that we have in the wee hours in the morning, 4:00 or 5:00 in the morning to get all the patients' blood drawn in the hospital, to get all the lab tests done very early so that patients who are ready to go home can go, free up a room for a patient may be coming in through the ER. All of those phlebotomists, that same number had to cover an additional area and had to take additional precautions because it was a COVID area.

So all of a sudden, we had to quickly figure out how to increase the turnaround of this lab testing early in the morning because if we couldn't get the lab tests drawn, if we couldn't get the blood drawn early, we couldn't get the tests resulted early. And the patients who were ready to go home couldn't go home early, their rooms couldn't get cleaned early, and other patients who needed the room to get out of the ER and into a room couldn't have a room. So it's a small issue, but we have to pivot quickly, think quickly about how to change what we do to accommodate an ever-changing problem.

The other issue is we have been lucky in our hospital that since last April, we've had the capability of doing onsite rapid PCR testing. So the best of both worlds, a result in under two hours but by the gold standard PCR. That's great, but we've had a very fluctuating number of these tests available to use, and, of course, everyone wants that test. So we've had to carefully monitor in conjunction with our nursing and medical staff leadership the number of tests we have on hand, which are rapid tests, and to be good stewards of the supply, count them every day and make sure that we are using them for very strictly applied criteria so that we have them when we absolutely need them.

Again, it took a lot of pivoting, it took a lot of advanced thinking, and most importantly, it took a lot of interaction and cooperation with the other parts of the hospital. So every day, there's a new challenge like this.

**Dr. Kisha Mitchell Richards:**

Thank you. It's so interesting that we are from such different areas, such different hospitals, but we have such similar stories, including the high points of that tremendous group effort. And one thing, another unique challenge with the phlebotomy was the COVID-positive patients in our environment. Remember, we weren't letting people into the hospital. So if you had COVID-19 and your doctor needed a blood test, we had to rapidly arrange, where did you come to get your blood draw? And I have to say we worked with a tremendous group of people. Our phlebotomists were phenomenal in that respect. And we would make appointments for these patients. They would drive up. We would take them into secure locations, get their blood drawn, and then do a full clean down and have these patients still have access because as we know, access is very important. This pandemic has made it abundantly clear that health disparities continue to persist in the US.

So let's talk about the CAP's concern when it comes to unequal access to testing, treatment, in vulnerable communities, structural racism and vaccine hesitancy. All of these things are interplayed. Now, there is very clear data from the CDC that black, Hispanic and Native Americans are about three times as likely to be hospitalized from the coronavirus compared to white Americans. Even more profound than that, this virus has also killed black, Hispanic and Native Americans at much higher rates, ranging from about 1.9 to about 2.4. So think about that. If you are black, Hispanic or Native American, you are somewhere in the two to two and a half times more likely to die from COVID-19 as a white person here.

So Dr. Godbey, I know the CAP applauds the Biden administration's creation of the COVID-19 health equity taskforce. Tell us a little bit about that.

**Dr. Patrick Godbey:**

Surely. Well, first, the CAP condemns racism and injustice in any form. We applaud the Biden administration's efforts in this area. The taskforce will be addressing disparities on several fronts, including data collection. It's developing recommendation to ensure the appropriate data is collected for contact tracing programs in communities of color and underserved populations. We will have a much better handle and understand much more the challenges that you just talked about, and we look forward to having an active role in the taskforce and in meeting these challenges.

**Dr. Kisha Mitchell Richards:**

Absolutely. So Dr. Hill, with that in mind, you've told us an example of some more advanced disease when patients have deferred care. Can you tell us some of the reasons that you've seen or your observations about why patients are deferring care?

**Dr. Kalisha Hill:**

Yes. Most of it is directly due to fear of COVID-19 exposure in our hospitals. Early in the pandemic and particularly during our surges, we had census that had been peaked and our nursing staff just working tirelessly to care for our patients as well as our physicians. And during those times, those numbers are communicated to the public. So as they're watching the news, seeing all the news stories about the number of inpatient COVID-positive patients increasing, particularly during the surges, they're very, very concerned and don't want to come to the hospital for fear of being exposed. And many people were just staying at home during the shutdowns anyway because they did not feel safe going to the grocery store or going out to visit family and friends. And so unless they felt some dire illness, they would not come to the hospital or their doctor's office either.

**Dr. Kisha Mitchell Richards:**

Absolutely.

**Dr. Kalisha Hill:**

So during these times, we've worked very hard to make sure that we communicated on a level that reached out to the community constantly to let them know that measures had been put in place to keep the hospital safe so that people can come in and receive their care.

**Dr. Kisha Mitchell Richards:**

Absolutely important. I want to emphasize what you've just said. Take the opportunity to reassure our patients that come back to the hospital, come and get your care. This could become a real public health issue going forward because some of these patients may no longer have insurance. Dr. August, what do you think some of the implications of this might be?

**Dr. Carey August:**

The very worrisome implication is that if patients are deferring not only care but also, and hard to say more importantly, screenings, then many diseases will present at a much more advanced stage, be harder to treat, more deadly, and just from a dollars and cents perspective, more costly to treat. Patients might need hospitalization more. So the important thing is as we have made progress in the past with screening for diseases, we need to get back there again. And this year of COVID and shutdown of a lot of our screening modalities in hospitals has set us back, we need to encourage everyone to not only seek care when they are not feeling well but also to remember how important their screenings are.

**Dr. Kisha Mitchell Richards:**

That brings to mind something we mentioned earlier, which is a very tremendously important program that the CAP has that I'd like you to tell us a little bit about, our See, Test & Treat Program and how it can help to bridge the gap and address some of these disparities.

**Dr. Carey August:**

I am delighted to tell you about that. The See, Test & Treat Program is the signature program of the CAP Foundation. This program was started 10 years ago by one of our pathologist leaders, the late Dr. Gene Herbek. And in this program, we provide operational and financial support for screening programs all across the country. In 2019, we had 16 programs. Last year, unfortunately, we could only have 10, but we're ready to do 14 again this year. In these programs, women who are under-resourced, either uninsured or far underinsured can come to a hospital site for free breast and cervical cancer screening. Not only is this free screening, but we tailor it to the population, thinking about what cultural and linguistic and maybe even just transportation barriers there are and try to overcome those barriers.

The wonderful thing about this program that sets it apart from every other screening program you hear about is that the patients get their result that day and are then connected with the healthcare system to arrange for their follow-up care right then and there so that you don't have a patient hearing about a diagnosis two weeks later and now being disconnected from the system and wondering what is she going to do because maybe she doesn't have insurance and where to go and how to get started. So it's that same-day process that has been so great and has actually helped us not only screen about a thousand women across the country every year, but has also helped us plug them in to get the care they need and ensure that they're going to get it. So we're very proud of this program.

**Dr. Kisha Mitchell Richards:**

I share your pride in that program. I can see you beaming as you speak to it. If you could just give me an example, a specific example of a case that you've encountered here and just briefly tell us what it meant for that patient.

**Dr. Carey August:**

I had the pleasure of meeting a woman, who took part in one of our screening programs several years ago. Her program was in Mississippi. She saw a flyer posted about the program at her church. She was a working mom and, of course, just put off going for her cervical cancer screening like so many people do. And, of course, how she was going to pay for that and any other treatment was a concern. But when she saw the flyer, someone convinced her she should go.

She had her cervical cancer screening at the See, Test & Treat Program and found out that she actually had cervical cancer, which was already in a somewhat advanced stage. Before she left the hospital site that day, she was plugged in to her follow-up appointments and treatments. The next week, she got a diagnostic biopsy, she got radiation treatment, and when I met her, she was a year out of her treatment and was cancer-free. And she became one of the biggest advocates for this, actually coercing friends into participating when the program came back the next year and driving them to the hospital site for their testing. So it was so rewarding to see somebody who could be alive for her children, thanks to this program and how it not only found her cancer but got her plugged into the treatment she needed. It's very rewarding to see.

**Dr. Kisha Mitchell Richards:**

That sounds wonderful. It's so amazing to have patient stories. And another high of this pandemic has to be that I have so many more patient stories in the last year than I've had maybe in the last five. There were times during this pandemic, at least two times a day, I would be on the phone with patients, either helping them get a test or explaining a result or clarifying, okay, they want a repeat. Just having some really good discussions and being able to be part of a clinical environment just really being there for our patients. Did anyone else have that experience? Dr. Hill?

**Dr. Kalisha Hill:**

Yes, absolutely. Yes.

**Dr. Patrick Godbey:**

Very much so.

**Dr. Kisha Mitchell Richards:**

So we've had a great discussion so far, but let's open it up to the media attending today for some questions. Let's start with the questions that were submitted. So let's go ahead and take the first question, which is from Usha McFarling with STAT News. The question is please let us know your thinking on how much of a concern the different variants are. Dr. Hill, can I ask you to address that question?

**Dr. Kalisha Hill:**

Yes. I will have to say that there is great concern and really understanding the different variants and how they have impacted various communities around the world. Some variants are more infective than others. Some people may be sicker if they have one particular variant over another. So it's very important that our testing platforms are able to detect all of these variants, and when necessary, we are able to send the virus testing collection that we received and send it to our public health departments to analyze, to really determine what type of variant is being identified in a particular patient. And that will give us more information over time to really see how the various variants are impacting the recovery of patients that are COVID-19 positive. So it's very important that our testing platforms are able to detect these variants so that people can receive the care that they need.

**Dr. Kisha Mitchell Richards:**

I do know that it's a question I get often as well with the variants, the vaccine, the variants, the vaccine, the variants. I don't want to diminish the importance of contemplating what do the variants mean, what are the implications? But I would like to remind everyone, have a greater focus on the vaccine, not the variant. Let's worry more about COVID-19. And our best way right now to protect ourselves with that, in addition to our usual measures of masking and physical distancing, is getting vaccinated, and that I think is a bigger concern for most people. But the vaccines that are currently available in the United States today have been shown to be effective against the variants that are in the United States today.

**Dr. Kisha Mitchell Richards:**

So as we think about variants and vaccine, think a little bit more about vaccine and a little bit less about the variants. It's a race. Let's race to get vaccinated.

**Dr. Kalisha Hill:**

Absolutely.

**Dr. Kisha Mitchell Richards:**

So the next question, thank you very much. So from Cheryl Clark with MedPage Today, I would very much like information on the new at-home tests and whether they're capable of detecting any or all of the variants we know are now circulating. And I'm going to ask Dr. Godbey to maybe touch on that one.

**Dr. Patrick Godbey:**

Thank you. The at-home tests are, and again, as I mentioned earlier, we need to define first, is it an at-home test that you simply collect the swab or collect the sample and then send it to a lab in another state? The quicker you get that, in fact it needs to be the same day that you send the specimen out, the better. The majority of the tests that are marketed in using that technique will detect the variants.

Now, on the other hand, the at-home test, each one needs to answer that question on its own. There was a new test approved by the FDA within the last 48 hours. The ones that use a nucleic acid amplification technique, it looks like they will detect the variants, but that's a question that each manufacturer needs to answer.

Antigen testing on the other hand is a bigger question. There are some antigen tests that we frankly don't know if they will detect the variants. The FDA has asked manufacturers of antigen tests to tell us about this. Will your test do this? The CAP has asked manufacturers of antigen tests. So I feel less comfortable about antigen tests than I do the PCR nucleic acid amplification test.

**Dr. Kisha Mitchell Richards:**

Thank you, Dr. Godbey. I share your concern about the antigen versus the molecular, the tests that use a molecular method.

Another somewhat related concern about some of the antigen tests is some of those, the false positives that occurred, did occur in testing in asymptomatic groups. And so that can have implications because if a patient is asymptomatic and take an at-home antigen test, for some reason, it comes up with a false positive, then you really think you're COVID-positive when you're not. And most of these patients, they took them, they wanted to travel, so it could have a greater inconvenience than the convenience of the at-home test. So it's just another point I just like to mention with respect to that.

Is there anybody else that would like to weigh in on the at-home testing and in particular, as it relates to this question from Damien McNamara? Speaking of at-home testing, I would like to know how reporting of results is done or not done. I leave the floor open for anyone who wants to take that question.

**Dr. Patrick Godbey:**

Well, as I said earlier, I'm worried about that because some of the at-home tests that are performed at home require either a smartphone or another light device to report the results. Well, that may well be a problem in some of our most vulnerable populations. I'd like to know what other people think.

But before we leave this, one other important point about all testing, and this needs to be emphasized, particularly with at-home testing, bad data is worse than no data at all. As you just mentioned, if you think you're positive and you're not, that changes everything you do. You can't go to work. But in some respects, even worse is when you get a false positive test and you go out and you go see your grandmother or you go to work and thinking wrongly that you do not have the virus and you do. Bad data is worse than no data at all. That's one thing pathologists do for a living, is to make sure that the tests that you get from laboratories directed by pathologists are as accurate as possible.

**Dr. Kalisha Hill:**

Yeah. He said something that really triggered in my mind, results. Laboratories take great pride in making sure their results are accurate. We literally live and breathe by every single test that we analyze and what that result is and where it falls in the reference range and what it means for the clinical outcome of a patient. So to have that component be outsourced gives us great pause because we know that within a laboratory setting, we have all the mitigation in place to make sure that those results are accurate. So that is the piece that I think that is most important that Dr. Godbey touched on.

**Dr. Kisha Mitchell Richards:**

I think just to piggyback on that too, certainly as a laboratory director, I will share this. If you come to get a test in my laboratory and you have an issue or a question or anything, you can call my laboratory. You can get me. You can speak to me. I can talk to you about your test. We can have a conversation. I can retest you. We are accessible. We may not be convenient because we're not at your home, but if you need me, you can get to me, and that you can't replace. So I'm not trying to diminish the convenience of some of these tests, but there are other factors to consider as you take these tests. As a single standalone time point at home perhaps, but as you want to continue through your course as we go through the pandemic, as you want to rely on something validated, tested on people who do this every day for a living, I have to say I'm going to stand up for my colleagues and plug the laboratory and the CAP and the accreditation process here.

So now that I've stepped off my little stand, another question I have here is in your cities, what are some of the more serious implications you're seeing in terms of deferred care? Dr. Godbey, could you tell us a little bit about what you might have been seeing?

**Dr. Patrick Godbey:**

Certainly. Deferred care is definitely a problem for us. Dr. Hill mentioned a case earlier. We see this in several patient situations, colonoscopies, patients who were scheduled for screening colonoscopies or patients who had symptoms. Many of those, our endoscopy suites were shut down during COVID-19. Then some of those patients end up testing positive for COVID-19 and their procedures were put off. By the time they came in, the adenomatous polyps were huge and some had colon cancer. It's an example of delayed treatment.

We had another patient, who broke a hip, but she was so afraid of coming in for COVID-19 and then our ORs closed because of COVID-19. But the long and the short of it is four weeks after she broke her hip, she had definitive surgery. So that took an already big procedure and made it a lot bigger with a lot more morbidity. We're seeing increased morbidity. We're seeing malignancies that are further along than they should be, and we're seeing preventable lesions that aren't as preventable as they should have been if we had gotten to them earlier.

**Dr. Kisha Mitchell Richards:**

Yes, we've been seeing that too. Once the hospital has started seeing patients again, we were seeing tumors that were bigger and more bizarre and things that would just take longer to render a diagnosis than we've seen previously.

So from our YouTube Live, I have a question. Is there a vaccine that is most effective for African Americans, and is there any vaccine that I should avoid? So my answer to that question is the vaccine that's most effective for African Americans is a vaccine you can get. And as we talk about health disparity and inequity, it is very, very clear that the percentage of vaccines that are getting into the arms of black, Hispanic and Native Americans is significantly lower than it should be when we talk about the condition. So I would urge, urge every single one of our vulnerable populations, all black Americans, all Native Americans, all Hispanic Americans, my Latinx community, any vaccine you can get is a vaccine you should get. Any of the vaccines that we have available now is the vaccine for you, if you can get it. We are hoping to work harder so that you can.

So since I've taken that question, I would like to ask Dr. August, can you speak specifically to some of the health disparities you've seen in your region and why is it so important to shine a light on some of these disparities? That's another question that I have.

**Dr. Carey August:**

This goes beyond just COVID testing and vaccination. We see this in many other areas. And just drawing on our experience from our See, Test & Treat Program across the country, we realize that not only are there vulnerable populations who don't have access to care, don't have access to insurance, perhaps don't have the money to be self pay, but there are also so many cultural barriers where people are uncomfortable having an exam by a physician. There are so many issues regarding health literacy that are important for these populations as well. So we have seen these disparities not only in our area, and I am in an urban hospital, so we definitely have seen this, but we know it exists all over the country.

And one thing our See, Test & Treat Program has taught us is it's a little bit different everywhere, but it all has that same theme. So care has to be not only effective care, but it also has to be culturally sensitive, how to approach a patient, how to engage a patient, and how to make sure that they go on to do what they need to do to be healthy.

**Dr. Kisha Mitchell Richards:**

Thank you. Thank you very much for that. So our hour is just about up. I think we all could have probably talked for a little bit more, but my thanks to our panelists who did a tremendous job in sharing their perspective and giving us some information as we continue to work through this pandemic. So Dr. Godbey, I would just invite you, do you have any closing remarks that you'd like to share with us?

**Dr. Patrick Godbey:**

Yes, I do. And thank you to Dr. Mitchell Richards and all our other panelists for this very informative discussion. I want to urge the media who joined us today to please continue to reach out to the College of American Pathologists for any information and comments when it comes to laboratory testing, including COVID-19, or for any follow-up information from today's briefing.

Please visit our new multimedia newsroom to view this briefing again and for other information about pathology and pathologists. Our next media briefing is scheduled in April, and we'll focus on the CAP and its ongoing advocacy efforts. As always, the CAP urges everyone to get vaccinated when it is your time. Continue to wear a mask, practice physical distancing, and wash your hands. Again, thank you for joining us today.

**Julie McDowell:**

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