Going Viral: Testing, Diagnosis and Treatment of COVID-19

with

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EPISODE 1: TESTING & DIAGNOSIS

ANGELA LECLERC: Hello, and thank you for joining us today. My name is Angela Leclerc. I'm a PA working in critical care in Portland, Maine. You are tuning into the Going Viral: Testing, Diagnosis and Treatment of COVID-19 podcast series developed by the American Academy of Physician Associates and supported by an independent education grant from Pfizer. The goal of this series is to provide education and tools to assist PAs and other clinicians in providing patient-centered care in the early recognition, diagnosis, and management of patients presenting in the outpatient setting with symptoms of COVID-19 caused by the virus SARS-CoV-2.

The COVID-19 pandemic is now entering its third year, and while cases are abating, new variants continue to emerge, along with the threat of new surges in infections. In addition to having three effective and approved vaccines in the United States, new therapeutics have arrived in the clinic that have the goal of preventing serious illness, hospitalization, and death.

Throughout the pandemic, PAs have played a critical role in helping combat COVID-19. As diagnosis and treatment shifts to the outpatient setting, PAs are ready to meet the challenge on the front lines. This is the first episode in a five-part podcast series focused on testing and diagnosis of COVID-19. I'm proud to be joined by Steph Podolski, who is a PA working in hospital medicine in Augusta, Maine, with a Master's of Public Health, and Dr. Sam Wijesinghe, who is a PA and Clinical Assistant Professor of Medicine at Stanford University with a Doctorate in Health Sciences.

To kick off this episode, Steph, would you please set the background for our discussion by giving our audience a broad overview about why we are testing for COVID-19?

STEPH PODOLSKI: Sure, I'd be happy to. Thank you, Angie and Sam, it's great to be here with you both today.

So, as we all know, at the start of the COVID-19 pandemic, not nearly enough Americans were being tested when symptomatic, mostly because there was a shortage of diagnostic testing capabilities. And even after the supply started to increase, shortages continued to occur depending on the regional increase in case rates in certain areas of the country, and the demand that resulted from the rise in cases. Despite all of this, testing remains vitally important to the overall public health of this

country, because it truly is the only way that we can reliably track the progression of this disease and prevent new infections.

Since the beginning of the COVID-19 Omicron variant, at-home test kits have been in high demand. These are tests that anyone can order or purchase and complete without physically visiting their healthcare provider. A number of companies are selling at-home tests authorized by the FDA, and everyone should know or tell their folks and patients out there that the Federal Government has free test kits available for every household. These test kits can be ordered online at www.covid.gov/test.

ANGELA LECLERC: Great. Thank you, Steph. That's a great segue to our next discussion about using the different testing modalities that are available. Sam, could you please describe the home antigen test that Steph was just telling us about?

DR. SAM WIJESINGHE: Sure. Yeah. First, thank you, Angie, and thank you, Steph for joining today. And I think we will be able to provide some helpful information through this podcast.

Antigen tests are FDA authorized under the EUA, that is Emergency Use Authorization. So, it is not yet FDA-approved. Antigen tests are aimed at detecting specific proteins found on the surface of the virus. Home antigen tests are good for people who have known exposure and currently have symptoms. I think that is an important point.

One of the things that I like to highlight, antigen tests have lower sensitivity rates than PCR. So, that means antigen tests are not very accurate when the viral load is small. We have seen some studies that demonstrate when people are symptomatic, antigen tests are estimated to be accurate approximately 70% of the time. So, the lower sensitivity rates with antigen test means false negatives are more likely with them. So, the sensitivity rate is one of the things that the FDA is looking into prior to considering full approval for the home antigen test at this time.

ANGELA LECLERC: Thanks, Sam. I'm wondering if there are any issues with accessibility with the home antigen tests.

DR. SAM WIJESINGHE: Yeah. You know, I think that's a very good question Angie, and thank you for bringing that up. So, there are still significant supply chain issues related to home test access. Cost can be a problem, transportation and then health literacy are some of the factors that impact home testing availability. And then also, I'd like to talk about that, you know, it is important to educate people what would be the best time for this antigen test. You know, if I can share an example, if Mr. Smith had an exposure with a COVID-19 patient yesterday, and if Mr. Smith is asymptomatic, doing an antigen test today is not helpful. I think we need to educate people like Mr. Smith that it will take a few days to detect COVID-19 with an antigen test.

ANGELA LECLERC: Thank you for that, Sam. That was really helpful and detailed. Steph, could you tell us about the PCR test?

STEPH PODOLSKI: I would be happy to. So, as we all know, the foundation of any diagnostic test is its accuracy. And as Sam alluded to, the FDA provides recommendations for COVID-19 test validation in its Emergency Use Authorization policy statement. And so, all of the tests that currently exist on the market are authorized, but not yet approved by the FDA. And this is because of the ongoing COVID-19 public health emergency. So, the FDA's current statement does continue to say that false results can still continue to have broad public health impacts. And as you've seen recently across the country in the news, many tests have been pulled off the market for this reason. And so as a result, the polymerase chain reaction test, also known as the PCR test, remains the gold standard for testing for COVID-19. This test is sometimes required for travel or return to work or school, although with the change in guidelines, this is not needed as much most recently.

The PCR test is a molecular test and will detect if the SARS-CoV-2 genetic material is found in a patient's sample. PCR test replicates parts of the virus, which means the PCR process is much more accurately able to detect small amounts of virus in a person's system. The PCR analysis process is highly sensitive, and as a result, this test is much less likely to have false negative results. The PCR test, because it's more accurate, can be used in asymptomatic people who have had recent exposure, and people who are early on in the stages of an acute viral course. It is much more likely that an individual will continue to test positive for quite some time, even after an individual is recovered with a PCR test as compared to the antigen test that Sam just previously described for us.

ANGELA LECLERC: So, that's the home antigen test, the PCR test. Steph, to round out the different types of testing, would you mind giving us a broad overview of the antibody test?

STEPH PODOLSKI: I'd be happy to. So, early on in the course of the pandemic, especially after vaccines came out, many people wanted to know if they developed antibodies to either the vaccine, or if they had the acute COVID-19 infection, they also wanted to know what their antibodies looked like. And for some time, this was available at local pharmacies. In the healthcare setting, an antibody test is a serology test that can detect SARS-CoV-2 in your bloodstream. Antibodies are the proteins made by your immune system that help to fight off an infection, as well as prevent recurrent infection in the future. The antibody tests that currently exist are not used to detect current infection. They use specific IgG and IgM quantification forms to detect if a person has had a past infection of COVID-19.

In the healthcare setting, especially where I work, we often see that someone will test positive for COVID-19 coming into the hospital, and they're entirely asymptomatic. That

individual may say specifically they had COVID about a month and a half ago, but we don't have a confirmatory test to verify that. So in my setting, what we'll do is antibody testing to determine if their levels are high enough to prove that they have, in fact, had a past infection. And these antibody tests really do help determine if someone is actually outside of that acute infectious period. And so, they've been vitally important within healthcare systems throughout the course of the pandemic.

ANGELA LECLERC: Sam and Steph, that was a great overview of the three different types of testing modalities: the home antigen, PCR, and antibody tests. Thank you. Now that we understand these testing modalities that are available, Sam, when and how should providers advise asymptomatic patients to test for COVID-19?

DR. SAM WIJESINGHE: Yeah. So, if someone is asymptomatic, obtaining a comprehensive history from the patient is very important. I would like to find out the following when I have a patient like that. I ask why they are testing. In general, they have a reliable explanation why they are testing. And I ask if they did the home antigen test and what was the result of the antigen test. This is in general a teachable moment with my experience. I let them know, if you are asymptomatic, home antigen tests can be false negative, then I would like to go one step further and explain why false negative of someone may lead to a life-threatening situation of someone else.

Let me explain what I mean by that. Patient A is young and asymptomatic and has a false negative test. In reality, Patient A contracted with COVID-19, and this patient lives with Patient B, who is immunocompromised, for an example, with heart failure and say, about 70 years old. So, to illustrate my point easily, let's say that this patient is unvaccinated, too. So, if this patient contracts COVID-19 from Patient A, it can be life-threatening and dangerous. So, if someone had a recent exposure to COVID-19 and asymptomatic, I would recommend PCR test.

ANGELA LECLERC: Oh, that makes sense, Sam. Thank you. Do you have any advice on the frequency of testing if the first one is negative?

DR. SAM WIJESINGHE: You know, depending on the test that they have done, let's say that somebody had exposure yesterday, and then they did an antigen test after 2 days. Most likely, it's not a reliable test. So, you know, I will recommend them to do another test after about 5 days. And then at that point, if they have symptoms, doing an antigen or PCR test will be okay. If they don't have symptoms, and if they are very certain that they had an exposure to someone with COVID-19, then doing the PCR test is probably a good idea at that time.

ANGELA LECLERC: Oh, yeah, that makes sense. So, PCR test: asymptomatic, known exposure, and remaining concern for harboring the virus asymptomatically. Great. Thank you. Steph, what about when you have a patient who is symptomatic, what's the advice for testing there?

STEPH PODOLSKI: My advice is to, if anyone develops respiratory or even GI symptoms, to be tested immediately. And once symptomatic, the antigen test would be a good first step. It's easily accessible, folks do not have to wait at a healthcare office for a PCR test, et cetera. Another time I would recommend a symptomatic patient be tested is if they've had a known exposure. And certainly, there are a lot of other illnesses going around at this time, but once symptomatic, anybody should be tested at any point in time, especially during this ongoing pandemic.

ANGELA LECLERC: Great. And how confident can these patients be in their test results, Steph?

STEPH PODOLSKI: That's a great question, and there's been a lot of hot debate about that across the country. As we highlighted previously for everybody, once symptomatic, the antigen tests, which are the at-home rapid tests, are quite accurate; 70% accuracy is actually quite high for healthcare. I think that if people are concerned about the accuracy of their at-home tests, they should go see their local healthcare provider, health clinic, and urgent care, or even an emergency department to receive a confirmatory PCR test. As we've said previously, those low viral loads early on in an acute illness could lead to a false negative result. But once someone has developed symptoms, the test on both ends, PCR and antigen, are very accurate.
And I do think it's important to highlight here that home testing is very important for community protection and public health. And by that, I mean that if somebody has a known exposure and then has developed symptoms, healthcare providers across the country are recommending that if that person can test at home, that's the best course of action, and then arrange a telehealth visit with their provider, if possible, if they have access to telecommunication or are able to do so. But we don't want that person to go out into public and then expose many other people in the process of trying to find out whether or not they may have COVID-19. Certainly, if they have progressive symptoms and are feeling very poorly, they should come in and be seen. And it's a fine balance between taking care of the individual patient and also trying to protect the general population. And that is what we've all been struggling with throughout the course of this pandemic.

ANGELA LECLERC: Okay. Changing gears slightly, you now have a patient who takes a home antigen test and it is positive. Sam, what does this mean and what are the next steps?

DR. SAM WIJESINGHE: Yeah, that's a very important discussion to have. I would say they should call their healthcare provider. This information can be very helpful when making public health-related decisions. For example, what areas might have the highest prevalence ETC. In general, if someone is symptomatic and has a positive antigen test, I actually take it as a reliable test. Occasionally, we might recommend doing a PCR test at that point. But in general, if they have done the testing at the right time - when I say at the right time after like 5 days, 6 days - from the exposure, and then

they have symptoms, then I take it as a reliable test and then go from there, you know, talk about treatment options.

ANGELA LECLERC: Great. And Sam, what about this constant evolution of quarantine guidance for patients and families?

DR. SAM WIJESINGHE: The quarantine guidance and isolation guidelines, I think it is important to point out these guidelines may change as we get to know more evidence-based information. Therefore, I encourage clinicians to review COVID-19 related guidelines constantly. I would be happy to touch on current guidelines on isolation and quarantine. If somebody has a positive test, that person will require isolation. If that's the case, if they have a positive test, isolate for at least 5 days, and then monitor your symptoms. That's the current guidelines as far as the isolation.

And then as far as quarantine, if you come into contact with someone with COVID-19, you should quarantine if you are not vaccinated or up to date on COVID-19 vaccines. So, what to do for quarantine? That is something important to highlight. Stay home and away from other people for at least 5 days after your last contact with the person who had COVID-19. The date of your exposure is considered day zero. And then a couple of other things, I think important. Wear a well-fitting mask when around others at home, if that's possible. And then in case if you develop symptoms, please get tested immediately and isolate until you receive your test results. If you test positive, then follow isolation recommendations.

ANGELA LECLERC: Thank you, Sam. One question about that. When a patient is positive and quarantines for 5 days, do they need to mask through day 10, or can they not mask?

DR. SAM WIJESINGHE: In my case, I would recommend masking 5 more days. And especially if that person had an exposure to someone with COVID-19, and if you know for sure that person had it, I would recommend masking for a few more days.

ANGELA LECLERC: OK great, thank you. Sam or Steph, would either of you be able to comment on whether a patient who tests positive should call the CDC to let them know?

STEPH PODOLSKI: Sure. I'm happy to weigh in. I don't think it's necessary that they call the CDC as their healthcare providers are reporting the data to the community health departments directly. However, it's not out of the realm of possibility. And if an individual wanted to call the CDC to get more information, or to be provided with some reassurance in addition to being provided reassurance by their healthcare provider, I think I would encourage that, the more information that anyone can have about an illness, especially a communicable illness, the better, I think. Would you agree, Sam?

DR. SAM WIJESINGHE: Yeah, I totally agree. And then one of the things I also like to highlight here. When people have home testing, they might have a positive result and they can be very mild, they might have very mild symptoms, and they might not even call the healthcare provider. So, I encourage them, please call your healthcare provider and let them know about the results. And even if you don't have symptoms that much, having that information is very helpful information for us to manage this pandemic.

ANGELA LECLERC: Great. Thank you for that information, both of you. Sticking with the patient who is positive for COVID-19, it's important as healthcare providers for us to know how long someone may test positive after being infected with COVID-19. Steph, could you comment on this?

STEPH PODOLSKI: Yes. So, the immune system typically takes about 10 days. It's about 10 to 14 to clear the virus, which is why the current CDC recommendations are that even after the 5-day quarantine, that all individuals who test positive wear a mask for the 10-day total period. And after that time, after the 10-day period, individuals with acute COVID-19 infections are no longer considered to be infectious at that point. It is important to note that individuals who have an acute COVID-19 infection can, however, continue to test positive for up to 3 months, especially on the PCR testing that I spoke about earlier because of that high sensitivity. And it's not recommended that folks retest again after acute COVID-19 infection in that 3-month period unless new symptoms develop.

ANGELA LECLERC: Great, thank you. That's very helpful. Sam, have you ever had a patient who has tested positive for two variants within a short period of time?

DR. SAM WIJESINGHE: Unfortunately, yes. When I saw this happening with my patient, with some of my patients, I did not like that at all. I was hoping that people may contract COVID only once. That was my hope and was thinking at the beginning of the pandemic. But unfortunately, that was not the case. I have seen patients contracting both the Alpha and Delta, and then I have seen some cases, they had Delta, after that Omicron. So, I haven't seen someone with all these three variants, but I have seen having two variants within a short period of time.

ANGELA LECLERC: Okay. Very important for healthcare providers to be aware of that. Sam, going back to you again, how soon can a patient, regardless of vaccination status, receive the COVID vaccine after being infected with the virus?

DR. SAM WIJESINGHE: They should wait to be vaccinated until isolation period is over. People who have symptoms should not get the vaccine. They should wait until they become free of symptoms. And this same rule applies to people who have been vaccinated with their first dose but need any additional or booster doses. And then people who have had a known COVID-19 exposure should not seek vaccination until their quarantine period has ended to avoid potentially exposing healthcare personnel and others during the vaccination visit. This recommendation to wait also applies to

people with unknown COVID-19 exposure who have received their first dose and are in need of additional or booster doses.

ANGELA LECLERC: So, if I understand you correctly, Sam, there is no need to repeat testing prior to vaccination. It's just based on quarantine and symptoms resolving, correct?

DR. SAM WIJESINGHE: Exactly. That's accurate, yes.

ANGELA LECLERC: Okay. Great, thank you.

ANGELA LECLERC: This has been a really great review, Sam and Steph, of the different types of testing modalities available for COVID-19 patients, their accessibility and reliability, when to use which one in symptomatic and asymptomatic patients, and then indications for retesting.

This concludes Episode 1 of our five-part series. I want to thank you, Steph and Sam, for joining the discussion about COVID-19 testing and diagnosis. I also want to thank our listeners for joining us. And please join us for Episode 2, where we will discuss risk stratification, early treatment, and coordination of patient care.

RESOURCES

For Providers

- Testing for SARS-CoV-2 Infection (NIH)
- Testing Overview (CDC)

For Patients

- covid.gov (HHS)
- Quarantine & Isolation Guidelines (CDC)
- Test for Current Infection (CDC)
- Self-Testing Guidance (CDC)
- Coronavirus Self-Checker Interactive Tool (CDC)