

Serological test validity and its role in patient recovery

Watch the AMA's daily COVID-19 update, with insights from AMA leaders and experts about the pandemic.

Featured topic and speakers

AMA Chief Experience Officer Todd Unger speaks with AMA President Patrice Harris, MD, MA, Chief Health & Science Officer Mira Irons, MD, and Assistant Director of Federal Affairs Shannon Curtis on updates regarding COVID-19 including the latest on antibody (serological testing) and its validity and role in patient recovery from COVID-19.

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Transcript

Unger: Hello, this is the American Medical Association's COVID-19 update. Today, we're discussing the latest on antibody, or serological, testing for COVID-19. I'm joined today by Dr. Patrice Harris, AMA's President, and a psychiatrist and former County Health Director in Atlanta, Dr. Mira Irons, AMA's chief health and science officer in Chicago, and Shannon Curtis, the AMA's assistant director, Federal Affairs in Alexandria, Virginia. I'm Todd Unger, AMA's chief experience officer in Chicago.

Antibody testing has been all over the news and yet its validity and the role in recovery remain unclear. Dr. Harris, what is the AMA's current stance on antibody testing?

Dr. Harris: Well, first of all, Todd, let's start with where we always start at the AMA and that's with the science and the evidence and the facts. And these tests are rapidly coming to market. There are over 100 tests in the market. These are the tests that are used or can be used to decide if someone has been exposed in the past to COVID-19. But I want to make sure that everyone realizes that these tests should not, at present, be used to determine if someone is immune or not. We still have a ways to go before we have the science and the data to back up that claim.

Dr. Irons: As Dr. Harris said, we feel that these tests, it's too early for these tests to be used to make individual decisions about people. And the reason for that is that, whenever doctors order a test, they

have to know what the test is testing, how to interpret the test and also what does it mean for the patient? With these tests that are currently on the market, the first question is, can you get false positives on the test? And there are many tests on the market that identify cross-reacting antibodies to other coronaviruses. You have to be sure that a positive is really to the virus that you're testing for.

The second is, how do I interpret the test? And there are considerations, there are special considerations with COVID-19 because it is a disease with very low prevalence in the population. And so there is an increased likelihood that a positive may be a false positive, as opposed to testing for a condition where there's a high prevalence in the population.

And the third is really the most important. And Dr. Harris just touched on that. This is a novel virus and a novel condition. We don't know what it means to have antibodies and whether that protects people. The AMA at this point, at this time, doesn't recommend that people make individual decisions based on this testing, whether to discontinue physical distancing, whether to go back to work, as a basis for immunity certificates of any sort or whether having antibody protects themselves.

Unger: Thank you. Ms. Curtis, how has this become a regulatory issue? And what is the AMA doing on this front?

Curtis: Well, in times of national emergency, especially a public health emergency present some very interesting questions, as far as the regulation of things such as tests, drugs like that are concerns. Since we are facing a public health crisis and a public health emergency, FDA has had to somewhat relax its typical processes and rules for getting things like tests approved so we can get them to the public sooner, faster.

With the serology test in particular, a lot of these were able to come to market very quickly with very, very few rules and really no real regulatory review at the FDA. FDA wanted to get these tests to market quick so they could understand them. People could start getting an idea of disease prevalence in society. Things like that. Quickly realized that we might need a little bit more review and some stronger guardrails around these tests because we were seeing such questionable performance from so many that were coming to market as well as some fraudulent labeling activity. Certain tests saying they were FDA approved when they weren't. They hadn't undergone full FDA review.

We've recently seen a policy change that we lobbied FDA for. They are coming up with some more strict rules around tests that have to get emergency use authorizations. Now anything that's a commercially available test has to get that EUA from the FDA. Some other tests can still come to market, laboratory developed tests in particular, without getting an EUA from FDA. But FDA has now also published some recommended performance standards that these tests have to meet.

We really encourage physicians, members of the general public to look to see if tests they might be using or recommending to their patients are those FDA tests that have been authorized under an

EUA and to carefully consider the recommended performance standards that FDA has published and to see what tests they're using, kind of where those stack up performance wise against the FDA recommendations. But AMA has worked closely with FDA, the White House coronavirus task force, particularly those working on testing, to ensure that we have the highest performing tests possible on the market and get good messaging out about how and when these tests should be used and how they shouldn't be.

Unger: Well, given that, Dr. Irons, talk to me a little bit about when and or what should physicians be using serological testing for? And does it have any benefits right now?

Dr. Irons: I think that it certainly does. I think that there are benefits from a public health standpoint to determine the seroprevalence of the condition in the community. Also to determine the incidence of asymptomatic infections and as part of a specific care plan. Some physicians are using diagnostic testing in addition to antibody testing to make decisions about patients' care plans in terms locations, where they should go into a hospital or to be prepared for elective procedures and things like that. Physicians should just understand the limitations of the test and understand what test they're using and use it appropriately within a care plan.

Unger: Dr. Harris, any additional thoughts?

Dr. Harris: I would just say, Todd, in light of the AMA's continued commitment to being a credible source of information, we did publish guidance for physicians, but I think also the public will find it useful. And it really talks about all of the information that we've discussed here today. Certainly the reasons to use it, those are limited as Dr. Irons had just said. But we really want to emphasize, we really want to emphasize that the public should not use a result of one of these antibody tests to decide whether or not they are immune. We know that many folks may want to use this test to determine if they go back to work, if people should go back to school, if they should go out in public. And we need to make sure that everyone continues to use the basic public health practices that work and that is wearing a face covering in public, staying six feet apart, no large gatherings.

And again, if you have the results of an antibody test, please take that test with you to your physician so that they can help you interpret the test. But it is not a substitute for the tried and true public health practices that we should all continue to do.

Unger: Lastly, on a related topic that's been in the news as of yesterday, it was just revealed that President Trump has been taking hydroxychloroquine, despite warnings of potentially serious side effects. Dr. Harris, you've talked about this before. What is the AMA's current stance on this drug being used as a treatment for COVID-19?

Dr. Harris: Well, Todd, again, starting with the science and the evidence currently, there is no evidence that supports the use of hydroxychloroquine for the prevention or the treatment of COVID-

19. We do know that currently clinical trials are underway in the hospital and under the close supervision of physicians. And so we need to let those trials continue and wait until we receive the data because hydroxychloroquine is not without significant side effects. Certainly one could have mild side effects, but certainly there are problems with cardiac arrhythmias, that's irregular heart rate and rhythm. And for a person who already has a heart disease, it could be fatal. And so we really need to make sure that we wait on the science and the evidence before the general public uses hydroxychloroquine.

Unger: Well, I've always been struck by one of the comments that you made recently where the question was asked, well what is the downside to taking this? And I'll let you repeat your refrain there.

Dr. Harris: Well, physicians always live by the mantra of first do no harm, and really all medications, even some over the counter medications, may have significant side effects up to and including death. Medications that I prescribed often as a psychiatrist have death as a very low probability risk factor, but it is the obligation of physicians to talk to our patients about all those risk factors. Someone who may have a preexisting condition that they may not know about, they could actually lose their life, again, in taking this medication or any medication that has significant side effects. Physicians always proceed with care and caution. And I want to say one more thing, the FDA has cautioned against using hydroxychloroquine outside of current clinical trials that are going on and or without the close supervision of a physician.

Unger: Well, that's important guidance. I want to thank you for your perspective and your focus on science. Dr. Harris, Dr. Irons, Ms. Curtis, thanks for being with us here today and sharing your perspectives. We'll be back with another COVID-19 update tomorrow.

In the meantime, for resources on COVID-19, go to the AMA resource center at ama-assn.org/covid-19. Thanks for being with us here today and take care.

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