Michael Anderson, MD, MBA, on effectiveness of monoclonal antibodies

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In today's COVID-19 Update, a discussion with Michael Anderson, MD, MBA, senior advisor at the Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response in Washington, D.C., about what physicians need to know about monoclonal antibody treatments and their incredible effectiveness in helping certain patients avoid hospitalization for COVID-19.

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Speaker

- Michael Anderson, MD, MBA, senior advisor, HHS Office of the Assistant Secretary for Preparedness and Response

Transcript

Unger: Hello. This is the American Medical Association's COVID-19 Update. Today, we're talking with Dr. Michael Anderson, senior advisor at the HHS Office of the Assistant Secretary for Preparedness and Response in Washington, D.C. about what physicians need to know about monoclonal antibody treatments for COVID-19. I'm Todd Unger, AMA's chief experience officer in Chicago. Dr. Anderson, thanks so much for being here today. While the number of COVID cases in this countries continues to decrease, monoclonal antibody treatments have become a standard of care for certain stages of the disease. Can you explain first the science of these treatments?

Dr. Anderson: Sure, Todd. It's a pleasure to be with you today. Up until November of 2020,

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physicians were faced with a terrible dilemma—a patient had turned positive for novel SARS-CoV-2, but wasn't sick enough to be hospitalized and all we had was really hope and prayer. Now, we have three, repeat three, EUA-approved monoclonal antibodies that have shown to be effective in this particular group of patients. They're symptomatic, they've turned positive for novel SARS-CoV-2 but, thank goodness, they are not sick enough to be admitted. The EUA criteria for exactly who those patients are has changed. We'll talk about that in just a minute.

The science is pretty straightforward. These are exogenous antibodies aimed at novel SARS-CoV-2. They bind the spike protein and they basically are an interim step until the patient can recover, generate their own antibodies and, of course, vaccine has really been lifesaving. They bind to the spike protein, that then destroys the virus and provides, I think of it sort of as a bridge, a bridge until the patient's own immune system can kick in, hopefully, via vaccine and then the patient is then recovered.

Unger: When you think about the window for treatment, when is use of this treatment most effective and which patients tend to benefit the most?

Dr. Anderson: Yeah, if you take one thing away from our time today, earlier is better, that the EUA says within 10 days of symptoms, but we've seen in studies coming in over the past several months, the earlier the better. Now, the EUA criteria has changed. This is breaking news with monoclonal antibodies. I know we sit here in June of 2021 a lot of things have changed as well, but there are certain high-risk patients that really need to get these therapies as soon as possible—the elderly, patients with pre-existing conditions and, recently, the FDA changed and added a couple of things. Number one, the definition of obesity went down to a BMI of 25, number two, they added pregnant women to the high-risk category, so pregnant women now qualify for these therapies.

The last line is specifically, or I should say really important for clinicians, and that is the FDA says, you as a clinician, you as the physician taking care of this patient think that the benefits outweigh the risks. That, to me, says two things. Number one, it really gives clinical judgment back to the clinicians, and number two, it says these are really becoming part of the fabric of everyday medicine, and you doctors, you tell us if you think this patient can benefit from these therapies.

Unger: When we were back in that the height of the pandemic, there were a lot of obstacles, let's just say, toward getting to what you said, which is early intervention here. Do you think some of those challenges, we've been able to move past them?

Dr. Anderson: I believe that's true. We've administered over 500,000 doses of these monoclonals so, somehow, we're getting across the barriers. In my assessment of the barriers to getting these therapies in are really in two buckets—one is, there has been some clinical resistance. Are these drugs really effective? The data's so preliminary. I'm harking back to the classic thinking that it takes almost a decade from a new medication to when it's standard of care and we've been trying to do this in a matter of nine months. But as you see the data come in, I'll talk a little bit about that in a moment,

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the data is overwhelming that in this high-risk group of patients that is not sick enough to be admitted yet, there is a 70%, repeat 70%, decrease in the need for hospitalization in those patients, so I think that the clinical resistance is really much less so.

The second is operational. This is very easy to say. You should administer monoclonal antibodies to high-risk patients. But there's some operational barriers behind that, right? This is currently an IV infusion, although there is a new subcutaneous route available. You have to infuse it over a half an hour, so that means you got to get an IV in, you have to have an area to infuse and you have to monitor the patients for an hour afterwards. I got to tell you though, I have seen and I've actually deployed with a couple of these teams, this country has really been innovative on how we bring these therapies to patients. We've seen in-home infusions, we've seen mobile vans, we've seen SWAT teams go to nursing homes when there's been outbreaks. Of course, hospitals and FQHCs are the backbone of this country, so I think that these barriers remain because we're still not getting the highest percentage possible of potential patients but boy, I got to tell you, I'm so encouraged by how the country has really risen to this challenge.

Unger: Well, that is really great news because I do recall in those early days that those kinds of operational practical considerations were such a challenge, but I'm really encouraged by the numbers that you started to talk about in terms of the benefits. Can you talk a little bit more about the benefits that we're seeing with monoclonal antibody treatment?

Dr. Anderson: Yeah. Slowly but surely, these therapeutic trials are coming in. Like I said, it's breaking news. Every week, there's something new, whether it's a new EUA criteria. Actually, as we sit here in June, there's a press release from the Regeneron corporation of a potential in-patient application, more to come on that in the future coming weeks. But the data is consistent in the stuff that we've seen, 70 to 80% decrease in the need for hospitalization.

That does a couple of important things. For that one patient and for the doctor, boy, that's terrific, right? That means that patient's risk of dying, that patient's risk of mortality or being admitted is decreased by an incredible percentage. The other thing that really speaks to me as a former hospital administrator, it's ICU and hospital capacity. That means that less patients are flooding the emergency departments, less patients are taking up valuable resources and then finally, if you think about it, the data is still early, this is more conjecture, there's decreased spread. If we can stop this viral load in a particular patient, then hopefully we have less spread within families, so the benefits are really incredible.

Unger: Yeah, that's like somebody coming home with the flu and you're a family.

Dr. Anderson: Exactly.

Unger: That can be scary for everybody else.

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Dr. Anderson: Exactly.

Unger: I'm hearing a lot, of course, in talking to a lot to folks about these different variants, the latest one that we're talking a lot about is the Delta variant. Are we seeing these treatments effective for variants?

Dr. Anderson: Yeah. The variants do cause us concern, the fact that we're not really to herd immunity yet and there's still pockets across this nation that have not achieved a high vaccination rate, that's concerning to those individual patients and to those regions. The second is that then gives the virus a chance to replicate and generate these variants. That's very, very concerning.

I find comfort in the knowledge that on a real-time basis, I'm talking about weekly, the FDA and the CDC and state health officials are making sure that the drug companies that produce this, I'm sorry, are testing these medications against these variants. Right now, the FDA, CDC and HHS are working in real time to make sure we're not going to be shipping product to a state if a variant of concern is not sensitive to that product. You'll see there's now nine, nine states where the USG, the United States government, is not pushing the Lilly product to the states for use. The variants are of concern. The government is monitoring it closely and if a particular region or state hits a percentage of a variant that is not sensitive to this drug, then we're not going to be shipping that medication. Bottom line upfront is the other variants are a concern. The two products that are procured by the United States government, Lilly and Regeneron, and now there's a third monoclonal antibody by AstraZeneca, we're testing those on a real-time basis.

Unger: Several months ago, when I talked to my physician to prepare about getting access, should I need this, she was very, very proactive in saying, "Let's get that test fast. I will track this down for you." Still in that process of a lot of practical obstacles. Now that we are where we are, what do you see as the physician's primary role in increasing access to use of these treatments and, particularly, in underserved areas?

Dr. Anderson: Yeah, it's really important, first and foremost, that physician has the relationship with the patient. I know patients have a lot of questions. "This is new. I don't completely understand what a monoclonal is. Is this safe?" The tragic stories I've seen, or that we've heard of, are patients don't feel that bad. It's day two of symptoms and they have a little cough, maybe a fever, "Eh, I don't know if I need this experimental therapy. I'm feeling pretty well." The physicians have to take the rallying cry of, "But we know the sooner you get these therapies, that's going to prevent you from getting worse and going down to what can be a terrible, terrible path of this disease." So the first, I believe, role for physicians is continue to talk to your patients. They trust you. You have that relationship. Talk to the patients about these therapies.

The second is more of the advocacy gene that I think physicians do so well, that is if you see your region, whether it's your local hospital, your health officials, your particular clinics aren't really offering

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or embracing monoclonals, figure out why. The data is showing these are very effective therapy at preventing the progression of disease. Be an advocate for your particular patients. Say, "Well, where are these therapies available?" If you don't have them, let's figure out how we can get them because it is an infusion, but it's still really pretty straightforward.

Unger: Well, that's good. I love your point. Basically, I think sometimes people are just tempted to say, "I'm going to shake it off and ride this out," but the downside of that could be incredible. This physician as an advocate is really, really important. How can physicians find out where to access this treatment locally?

Dr. Anderson: Really, three ways—combatcovid.hhs.gov is our website. We've got resources that regionally show, you're in Cleveland, Ohio, these are the institutions that are infusing, so it's easy that way. The second is I think the great majority of physicians across this country do have some relationship, either employment or medical staff privileges. Reach out to your local hospital, "Are you offering this? What else can we do?" Then I also think there's very innovative ways. I've had the honor of working with federally qualified health centers and urgent care centers and infusion centers that have really taken this on as a part of the fabric of what they're offering to patients. Vaccine is really important and we can't diminish how important vaccine is and who knows what boosters are going to mean in the coming year, but I think there's great potential for innovation in physicians offering this in their practice.

We've also in the federal government, I'm a contractor for the federal government, so I don't speak on behalf of the USG, but we've seen really innovative ways where reimbursement has been increased for giving these therapies so that we say that innovative clinics, FQHCs, what have you, we also understand there's a reimbursement element to this and I think CMS has been really responsive.

Unger: Excellent. You mentioned earlier that some physicians are skeptical because of the EUA status of this treatment, or the fact that we're still at the early stages of research, or even because of misinformation, which there obviously is a ton out there. What is your message to those experiencing hesitancy in referring patients?

Dr. Anderson: Yeah, I think that the data is becoming overwhelming and I don't use that word lightly. This consistent 70 to 80% decrease in the need for hospitalization in patients is consistent throughout the studies. I do think it points to something that we've been saying within the United States government, I'm sure the AMA and others are saying, "We've got to assess how to do this better next time. What are the lessons we've learned during this pandemic?"

This is just Mike the physician speaking as a personal opinion. I do think this whole notion of an EUA, how physicians understand the process and how, quite frankly, we get data back to the docs in a quicker basis. I'm a physician in Detroit, Michigan. I have had the courage to open up a monoclonal or refer lots of patients. I think we, writ large, academic medicine and the government, have to get better at getting EUA data into the hands of physicians to say, "Thank you for the courage to stand up and

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do this for your patients, but here's the data that this has generated and this is what it's showing as we emerge in this crisis." I think that's, to me, a pin in something that we have to get better for because there will be more pandemics, right? We have to make sure we're better prepared for the next one.

Unger: That's a really good point, especially when you think about how much we've learned and the pace of which the learning has occurred over the past year, it's been reasonably intense, let's just say, for that. You mentioned the outline for the types of patients that are best suited to this kind of treatment. Are there any side effects or guidance on vaccination after receiving this kind of treatment that we need to make physicians aware of?

Dr. Anderson: Yeah. That comes up a lot. The EUA guidance says if you received the monoclonal antibody you should not, repeat, not get vaccine for 90 days. I think some patients have said, "Well, I want to get the vaccine. Does this therapy preclude me from getting it?" Well, the problem is if I'm ... vaccine, I haven't seen the vaccine, and I'm positive for novel SARS-CoV-2, we got to take care of you now, right? We'll get the vaccine, but these antibodies are taking care of you now and fighting the virus with this exogenous antibody. We will get you the vaccine in 90 days, but let's get through this particular hump in the road.

There's an interesting second set of patients. Those are patients that have been immunized, either one or two doses of the vaccine, and yet they turn positive. I think we've had more and more clinicians reach out and go, "Do they qualify for the monoclonals?" Well, I'd come back to that new EUA. This is in the judgment of the clinician. But once again, Mike's personal opinion, if there's a patient in front of you whom you're worried about who has tested positive, obviously, the vaccine for whatever reason hasn't fought the virus off. Very, very rare, but it does happen. I think monoclonals are a really good potential therapy for that patient because once again, we've got a short-term window. We have to get that patient through and hopefully improve their outcomes.

Unger: I'm just curious, why the 90 days in between administering monoclonal antibodies and getting vaccinated?

Dr. Anderson: I think the thinking is, once again, this is Mike's teleologic thinking, not based on a lot of science, I think that this is you've already been infected, you're going to mount your own immune response for a while, so this vaccine isn't really going to do you a whole lot of good, so let's give you the monoclonal. Let's see what the half-life is, probably 30 days, and then let's wait a little while until you get the backseat. That's, once again, Mike MacGyvering together the explanation but I think, once again, the bottom line is I am positive for a novel SARS-CoV-2, so I need to get over the hump of this disease and then worry about vaccine a little later.

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Unger: I get that. Thinking toward the future, is there still going to be a need for monoclonalantibodies down the road once the majority of people are vaccinated? I think you answered that alittle bit. What's your view there?

Dr. Anderson: Yeah, I think these are important tools for clinicians. It's getting more and more interesting and quite frankly, sometimes a little confusing because there are new products coming down. I think from my perspective, the great relationships the United States government has built with academic medicine and with terrific societies like AMA and with local health officials, those bridges and structures, I think, are going to be really important going into the next year because God forbid we do have a dust-up of Delta or the unvaccinated population feels significant outbreaks. The data is really, really clear—these therapies help those patients.

The second thing is there are novel and interesting medications coming down, including potential oral antivirals, as I mentioned, breaking news, potential in-patient use of these therapies. I think these therapies are really here for the long term. I think, once again, we've got to take lessons learned from what went well and what didn't go well, but I think that the physicians have to stay current on what are the particular indications for these therapies, how are the variants impacting that, to your good point, and I think these therapies are going to be around for a while.

Unger: It really is just another miracle of the past year in terms of effectiveness. It's really terrific news.

Dr. Anderson: Truly.

Unger: Dr. Anderson, thank you so much. We've learned a lot and I hope our audience has, too. Appreciate you sharing all that data information about monoclonal antibodies. Just to repeat the website one more time for physicians who are watching or listening, it's combatcovid.hhs.gov. Go take a look for more information. We'll be back soon with another COVID-19 Update. In the meantime, additional information on the AMA site, ama-assn.org/COVID-19. Thanks for joining us today. Please take care.

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