Ep. 6: The Omicron Variant: Where are we now, and what is the future for testing?

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Matt Hittle: Hi and welcome to another episode of Akin Gump's *OnAir: Health Care*. My name is Matt Hittle, I'm a senior policy advisor here at Akin Gump.

Dr. Mario Ramirez: And I'm Dr. Mario Ramirez, a consultant here at Akin Gump.

Matt Hittle: Dr. Mario, we have a great episode today. We've got Dr. Michael Mina, formerly of Harvard, and now with a company called eMed, to talk about COVID.

Dr. Mario Ramirez: Absolutely. I think this is going to be a really interesting discussion. We're going to spend some time talking about where we are with the pandemic, what we're seeing from the Omicron variant. And I think even perhaps more interestingly for some of our listeners, a little more about eMed's platform and what the future holds for things like digital point-of-care and testing to treat without having to even go to the doctor's office.

Matt Hittle: Yeah, I think there's a lot of promise in this technology. We're already reaping some interesting rewards from the proctoring technology they have. And, so, I'm excited to learn more about it. So let's jump right in.

Dr. Mario Ramirez: Today we're joined by Dr. Michael Mina. He's the chief science officer for eMed, which is a digital point-of-care platform providing verified testing and access to prescription treatment. Prior to joining eMed as the chief science officer, Dr. Mina was an assistant professor of epidemiology at the Harvard Chan School of Public Health. He was also an assistant professor in immunology and infectious diseases at the School of Public Health and the associate medical director in clinical microbiology in the Department of Pathology at the Brigham and Women's Hospital at Harvard Medical School. Dr. Mina is the author of hundreds of articles across a number of news outlets as well as print. And we're very fortunate to have him join us today. Welcome to the show, Michael.

Dr. Michael Mina: Thank you so much. Happy to be here.

Dr. Mario Ramirez: So Michael, other than your professional bio, can you give us just a quick introduction and tell us a little bit about yourself?

Dr. Michael Mina: Sure. I live in Boston. I'm about to move to Miami actually, to serve as chief science officer at eMed, as you mentioned, and I've been in the infectious disease and epidemic monitoring and tech development world for a very long time now, and I've been in academia as a physician and researcher and now am happy to be venturing out into things outside of academia.

Dr. Mario Ramirez: Great. Michael, I will ask you the question that a lot of folks ask me and which is maybe the hardest question to answer, but recognizing that this is December 22nd, and we have a little bit of a post-production lag, can you tell us a little bit about where you think we are in the pandemic, particularly with the oncoming of the Omicron variant, and where we think things are going to be headed as we head into the new year?

Dr. Michael Mina: Well, where we are, if we zoom way out and we look at this pandemic for what it is in its totality, we're absolutely on the downslope of it. And that doesn't mean that the virus is ever going away—it won't—but the importance that the virus has to human health will just keep diminishing. And that's because we're building up immunity. We have vaccines, the most important tool in this pandemic. We also, for better or worse, obviously mostly for worse, but from an immunological perspective, we have a lot of infections that have spread across the globe. I bet over two-thirds of all Americans have been infected, if not more. Certainly by the end of Omicron, it will be more. And so what that means is we have built up this large cushion of immunity in adults across the human population and children that's going to continue protecting us over the coming years and decades. So I do think where we're at in the global scheme of things is that we're on the downslope. It's just Omicron is an example of how the downslope can be a bit bumpy.

If we don't zoom that far out, and we ask, okay, where are we, it's now December 22nd as we speak, we're in the midst of another crisis. And of course that's Omicron. It is sweeping the country, it's sweeping the globe at breakneck speed, it will continue. It will probably infect a remarkably high number of people, and many of those people, despite vaccinations and preexisting immunity, will unfortunately go to the hospital. And, of course, many people with no preexisting immunity or vaccines will go to the hospital at higher rates. And, so, that's going to run the risks of overloading ICU beds and hospital stays. And that is a problem, and, of course, we cannot forget, although we've become numb to it, that every single day we have the equivalent of four commercial airlines' worth of people dying of this virus. So we're not out of the woods, unfortunately. And Omicron is certainly giving us another slap in the face, I would say. And in the United States in particular, the wealthiest nation in the world, it's showing us just how important it would have been to be prepared for it.

Matt Hittle: Well, you talked a little bit about the transmissibility, the virulence of Omicron. Let's talk about testing and the role you think it should play in the response to this variant. If the virulence of Omicron is lower, and it doesn't cause disease that's all that severe, but it still overtakes the Delta variant, what does the future of testing look like? Do you think it will be just as important as it currently is?

Dr. Michael Mina: Testing to me has a few different roles. You have medical diagnostic testing, and that's where you want to take personal action that is to your benefit. Let's say Pfizer gets its EUA [*Emergency Use Authorization*] soon, and people can benefit from getting an antiviral that will have a 90% efficacy to keep you out of the

hospital. That's a real benefit. And, so, if you get symptoms, and you want to test with the intention to potentially get treatment, testing like that won't go away.

That is medical diagnostic testing, and we've been doing it for eons. But the majority of testing we've talked about during this pandemic has actually been a different kind of testing. It's testing for public health. It's testing where the consequences of becoming positive are not those of your own health benefit, but they're the consequences of testing positive for most people, benefit the people around you. You end up isolating, which is not medicine, it's public health. No doctor would prescribe isolation to anyone. And that type of testing will have a persistent use throughout 2022.

But it's not going to be a long-term, forever type of testing where people are just trying to test themselves before they go to a gathering. Omicron in particular has made the role of fast testing ever more important. People have unfortunately mixed this up a bit. And I could talk about why, but the need for very fast, rapid testing has only increased with Omicron because the virus spreads so quick. And all of the testing modalities we have are going to lose a little bit of their efficacy to diminish spread because of how quickly this virus moves. But it doesn't mean that testing itself is not still going to be greatly limiting spread if you do it widely enough.

And, so, what we have heard recently is Omicron's spreading so fast. People are getting symptomatic, and then they don't turn positive on a rapid test, for example, for one or two days after their symptoms begin. Symptoms are starting earlier with Omicron, so people are testing earlier in the course of their infection, so that's part of it. But regardless, the test will still work. If it turns positive on day two, then that's days two, three, four, five, and six that somebody is able to take action and isolate away and not infect others as much. And, so, sometimes we only see the gaps in public health efforts, and we don't see where they're working because when they work, it's really a non-event. So it's hard to keep our eye in the ball. You really have to bank on mathematics to maintain trust that public health efforts actually do anything.

Dr. Mario Ramirez: Yeah, that's such a great point, Michael. The wins and the things that are going right don't get enough press, unfortunately.

Dr. Michael Mina: Yeah. I often say how no media reporter in their right mind would ever be interested in writing about some birthday party that had no outbreak, unless they're writing about birthday parties. They just would never write about it, but the moment there's an outbreak at a birthday party, then that's all that gets written about. So what it does is it causes, even if it's small gaps in effectiveness of a given public health effort, like a rapid testing before parties or before gatherings, unfortunately what happens is the only thing that people will ever see in the media or hear people talk about is when it doesn't work. And, so, that very, very much skews all of our thinking around what's useful.

And we actually saw a great example of this at the White House during the Trump administration, when there was an outbreak, there was a super spreader event in the Rose Garden, and what I watched in the White House was an administration that didn't take many precautions, except for tests, manage to go for 180 days in 2020 with no outbreaks whatsoever. But nobody talked about the fact that the Trump administration was not having an outbreak on every day that

they didn't have an outbreak. It wasn't until the Rose Garden event that people to this day look at and say, look, rapid tests don't work to keep you safe. But the denominator wasn't one, the denominator was 180. It's very important to keep the denominator in mind with public health but it's very, very hard to do.

Dr. Mario Ramirez: Such an interesting point, and to maybe to dive into that a little bit further, yesterday the Biden administration announced that they were going to be distributing or at least making access available to a half-a-billion tests for free to the American public. What was your reaction to that announcement?

Dr. Michael Mina: Well, as you know, I have been driving an effort to raise awareness around the public health benefit of testing. To me, testing is knowledge. It's the only way we see the virus. It's not some big medical enterprise. Testing is simple. It's something that allows people to be empowered to know if they're infected and take action to help stop spread. So, I've been really pushing for almost two years now for wider access to testing. I started a large testing operation at Harvard and the Broad Institute, which is probably the nation's largest, highest-volume PCR laboratory testing program. And that was back in February of 2020, so it's been a very long time trying to get the administration and the public and the scientific community and physician community to understand just how crucial and critical these tools can be. And, so, I recognized that there was a baseline two years ago of really very little understanding about rapid tests.

Most medical communities pushed them away and said they're garbage, and it took a long time to develop the understanding that a test that can be used frequently and accessibly is much, much, much more powerful than a one-off PCR test used for medical purposes. And so if we fast-forward two years now, I'm heartened, I suppose I could say, that the Biden administration is recognizing these tools as very important tools in this pandemic. 500 million sounds like a big number, but when you have a country of 350 million, it turns out 500 million isn't a huge number. But I look at this as just the seed that's going to start the snowball rolling.

And once 500 million are here, it's not going to be immediate, it will be over January, February, March. If they're becoming useful to the public, then we'll probably start to see more and more. And, so, I think that this is a very good start. I wish that it was a year and a half ago. I wish it was a year ago, six months ago, but you can't reverse time. So I'm very happy to see efforts and momentum at the White House moving forward at the moment.

Dr. Mario Ramirez: On that point, one of the concerns, or at least one thought that crossed my mind about the announcement, though, was that these are all rapid antigen tests that are distributed, which we assume they will be. Those don't necessarily tie into our public health surveillance infrastructure that is already tenuous at best. And I was a little bit concerned that putting that many tests onto the market in some ways will make it harder for us to track where Omicron and other variants are headed. Do you have that same concern, or how can we leverage those tests that are going to come onto the market in a way that'll help us better track what's going on?

Dr. Michael Mina: I certainly do have that same concern, because I've been listening to not just the public health experts like myself, but I've been listening to the state laboratories, to the departments of health in individual states and to the CDC. And that has

been one of their concerns about rapid tests from day one: How can we give people access to tests in their home if in doing so we lose track of where the virus is because they can't be reported reliably? This is specifically one of the reasons I left academia to join eMed, was to solve this problem. eMed is a distributed platform that allows people to test themselves from the comfort of their home, on their couch, in their hotel room, wherever they might be. It allows people to test on their terms and have reliable reporting to public health, have potentially downstream benefit like medicines, like Paxlovid and Regeneron.

And, so, we have the tools, actually, to convert what is otherwise just sort of a single test in a home that nobody knows whether or not it's been used, to a very, very powerful public health monitoring tool to get us through the rest of this pandemic. And I think, as an example, what we could do is we could say, if you are asking the government for a free test, or if you're asking your insurance company to reimburse your test, both of those that Biden administration has pushed forward now, then you also have to be giving something back in the form of public health, where you have to use your test in a way where you can report it.

And eMed is one of those systems that could enable that reporting, because there's a proctor who watches you, on your phone or a computer, do the test, validates who you are, verifies your result and is responsible for pushing the information to the public health laboratories. That to me is a good compromise in terms of giving people access to tests on their terms in their home, making programs work like tests-to-stay and travel testing, but while still getting the public health reporting. And we don't have to just give the tests away for free and say go at it, we can actually create strategy and structure to this. It will make everything much, much more valuable in terms of getting rid of this virus or at least the importance that the virus is having on our populace.

Dr. Mario Ramirez: Absolutely. And we're actually going to dig into eMed here in just a second. I have one other question that I get often and I'm sure you do as well, which is, how certain are we that the existing tests that we have now will continue to pick up new variants like Omicron? A few weeks ago there was some reporting about sort of a sub-variant that didn't have what folks called S gene dropout, which is sort of a peculiar piece of genetic code that we've used to detect the virus so far. Do you have any concern about that and where that might take testing as we head further into the new year?

Dr. Michael Mina: I don't. And that question that you raised about some variants of Omicron not eliciting the S gene dropout, it's not that they weren't detecting Omicron, it's that they weren't able to differentiate Omicron from Delta. And, so, in general, the tests are still working. Molecular tests, many of them do target the spike protein, or they target the RNA that makes the spike protein, and that is the protein that is mutated in Omicron for the most part. The rapid antigen tests, and I want to be clear, many PCR tests detect multiple targets, so they still work, but as the FDA came out and said the other day, there are a few molecular PCR lab tests that are not working for Omicron. The nice thing is molecular tests are pretty simple to change, and so that will be worked out. People shouldn't worry about it.

For rapid antigen tests, for some reason a lot of people have thought that these will not detect Omicron. It's myth. Somehow these things go viral. The rapid tests detect a part of Omicron or of just coronavirus in general that is not mutated

much in any of the variants. It's called the nucleocapsid, it's an actual protein, and the rapid tests grab a protein, which is like a building block of the virus. And that building block does not mutate very much.

In Omicron it has four mutations. It's not a lot. We know that two of them have not caused errors in the past with rapid tests because they were in Alpha or Delta. And we know that two of them are just not insights that are targeted by the rapid tests. So we feel very confident that the rapid tests in production today will detect Omicron. There's no basis to expect that they would not detect Omicron. Given the same amount of virus with Delta or Omicron, they seem to work very much the same.

Matt Hittle: The last piece I want to get into before we talk about eMed is the administration's move to require vaccination and testing in the private sector and for federal contractors. We all know that these regulations are now tied up in the courts, but we think we're getting closer to a resolution here. On this past Friday—again we're speaking on the 22nd of December here, this moves quickly—the 6th Circuit Court of Appeals reinstated the OSHA ETS [*Emergency Temporary Standard*] mandate. That was followed by several appeals with the Supreme Court and requests from the court to submit briefs by December 30th. So that puts us on a course for a decision in the new year. Now how do you think all of these legal machinations impact employers, how should they be thinking about testing and the implementation of a mandate, and are there ways employers can use testing to make the workplace safe in a manner that is logistically and financially feasible?

Dr. Michael Mina: There certainly are. Without going into detail about whether I think the mandate itself is the right approach or that the ETS approach is correct, what I can say is it's a real effort to make workplaces safer. Vaccines are the best thing we can do. But for any employer who's really trying to ask the question, how do we make our workplace safe now that we know that the vaccines are only moderately, at best, reducing transmission, especially with Omicron, what other tools do we have in our war chest against this virus? And that's where rapid tests become extremely important. We have masks, we have filtration and distancing. We have not moving at all and not going to work. These are all options. But one of the best tools that we have is to just know who is positive before they get to work each day, so that they don't come into work if they are positive.

That's where rapid testing is very, very valuable. You can do it 10 minutes before work. You can do it two hours before work, whenever it needs to be done, ideally within hours. And it can be done in a reliable and authenticated way, which we can talk about what eMed brings to the table for that. But whether you have people doing the swabbing and testing in your lobby of your building, or you're using digital distributed systems that are able to authenticate who used a test each day, there are a lot of tools now that can greatly reduce the risk that somebody's walking into your workplace positive. And rapid tests won't be perfect. They will not be perfect, just like masks and vaccines are not perfect, but they are one of the most effective tools to be able to identify infectious people and keep them out of the workplace.

And so even if they miss 10% or 15% of people who are infectious on their first day of being infectious, that means they're catching 90% or perhaps 85%, which is a massive, massive win in terms of preventing the number of outbreaks that

you might otherwise see across your industry. I do believe that eMed is really at the front of making that a reasonable and accessible approach for many companies to take as we move into 2022. We have digital distributed systems to take all of the labor and all of the effort off of the employer, or if it's for schools off of the school system, and really allow individuals to take control, but in an authenticated way on their own.

Dr. Mario Ramirez: Interesting. And so what do you think the next three months, six months, even the next year look like for eMed, Michael?

Dr. Michael Mina: Just to explain quickly what eMed is, it's a digital proctoring platform that, essentially at its heart, I think there's a lot of ways it can be used, but in the case of COVID testing, it's an authentication and verification platform. You have a rapid test, you want to use it at home, but you also want that result to be trusted by your employer. You want that result to be trusted by TSA and CDC so you can reenter the United States. You want that result to be reported to public health agencies, whatever the purpose. You need to somehow be able to give people confidence that you actually used the test, that you actually stuck the swab in your nose, and essentially that the result was actually negative or positive, especially if you're going to be getting treatment. We don't want people faking a positive to start hoarding Paxlovid.

There are disincentives to being positive. So most people who are positive might not feel inclined to report their positive to their employer, especially if they're lower income. So eMed changes the equation here. It's a system that allows you to scan your test; you scan the box, a proctor pops up onto your phone or your computer, or you just go to a website, and a proctor pops up. They ask you to say who you are, you show them some form of identity, and they watch you then do the test, and you actually get a laboratory report that is an official lab report with reporting and enables you to take downstream action based on that. It's an authenticated report, so if you get an eMed report that says, look, I used this test at home today, then the person looking at that report can be pretty darn sure that yes, this person is telling the truth, and they were negative.

So I think where this brings eMed is as we move into 2022, tests are going to be distributed widely as we've heard, potentially 500 million for free. We're going to see insurers being asked to pay for many people's tests, but insurers don't want to pay just for a test. Insurers pay for a test result. And, so, eMed is going to help facilitate a lot of this, where an insurance company might say, well, we'll reimburse your rapid test, that's fine, but we need to see that you actually did use it and you didn't go to Walgreens, buy five tests and then sell them on the street. And I think that that's very reasonable for an insurance company to want that verification.

As I speak to members high up in the government, across many areas of government, there's increasing urgency and interest in figuring out how to keep reporting from these rapid tests that are being distributed, so there's a keen interest in how eMed will be able to authenticate these results through our digital platform. So I think we're going to be very, very busy in 2022, but also along with it, I came on as the chief science officer. I'm not a marketing person. I'm just trying to help do public health. And part of that is accelerating clinical trials. How can we get more tests authorized? How can we get better drugs through the FDA process quicker?

One thing I'm wanting to do and where we will bring eMed is to really use our platform to massively accelerate the pace of clinical trials, because we have these proctors that sit in front of people and watch them do whatever it is they're doing. So if somebody's wanting to join a clinical trial, but that trial needs to have verification that somebody's actually using the medicine each day and or using the test, whatever it might be, they no longer have to come into a location and we don't have to have a nurse go out to their home to monitor the process. We can actually do it digitally at a very, very high scale. We have tens of thousands of proctors standing by all the time so there's no wait. That's one of the major areas I want to see eMed go, is to essentially help facilitate clinical studies and clinical trials.

Matt Hittle: Well, that was really interesting. And I think you have a hard stop, so I want to be respectful of your time. But the last thing I just want to note is really quickly, obviously you've mentioned the potential for eMed to facilitate clinical trials in a novel way. And obviously eMed's platform is not COVID-specific, although I think Mario and I have both used it for COVID tests to learn about the platform and I had no issues. It worked smoothly for me. Just thinking about the future, you've got the ability now to do a proctor test for virtually any respiratory infection, other diseases, UTIs, STIs, etc. You've got this kind of end-to-end modality that could expedite testing to treatment. How is eMed going to move forward, branching out post-COVID, if you will.

Dr. Michael Mina: Yeah. The first step is that, within COVID, we're going to be working on our test-to-treat platform, which effectively as the treatments from Pfizer and Merck get authorization from the government, those drugs need to be started very early, very early within COVID symptoms, within the first few days to be maximally beneficial. In the current landscape of testing, that will be very, very difficult. Most people don't even go and get a test until at least two days into their symptoms. And if they're getting a PCR test, it might not come back for two or three days. So then by the time they get a result, they're beyond the window of benefit.

So the first place that we're going in terms of our future direction is to start with COVID and to say, we can actually pre-position tests so the federal government can pre-position tests in at-risk people's homes, maybe it's CMS, or maybe it's the VA hospital system, or others. Put three or five tests in people's homes who are at-risk and say, if you feel any symptoms, use this test, don't be shy. We'll send you more tests and they do the testing part. And as people use the tests, they do it through a proctored pathway with eMed or with services like eMed. And if they are positive and they fit a certain demographic, certain age category, etc., there can be an immediate prescription or linkage to telehealth, but ideally an immediate prescription to get Paxlovid, the Pfizer drug, for example, and have it be delivered to their doorstep that day, reducing the time that it would take for somebody to get treatment started from perhaps four or five days to 12 hours. And that's going to be our foray into how do we really use this system to help people in a medical way.

There is no reason in the future that any parent should have to bring their child into a doctor's office to find out if their child has strep throat. The tests are simple. They're very similar to the rapid COVID tests. And what we want to do in the future is say, let's create a digital point-of-care system where it's essentially a point-of-care because you have a place and you're doing the care, but instead of having a nurse actually do the swab, you have maybe a nurse or a proctor watch

you and guide you through doing the swab so that your kid can get their mouth swabbed and be able to find out if they have strep throat without ever leaving the home, and then get an immediate prescription to treat that. Perhaps they can bring in a telehealth or their pediatrician, but maybe the pediatrician just gives them a standing order should they be positive.

So that's the direction that we're going, is to really start benefiting people from a medical perspective, which is why we're not ePublicHealth, we are eMed, because that's sort of the longer term role and the niche that we want to fill. And this really does become extremely important, given that RADx and the NIH have now put massive amounts of money, billions of dollars into tech development for technologies that are going to facilitate at-home testing.

All of a sudden we have a massive number of new technologies that are going to come online over the coming few years. And eMed is going to be very, very well positioned to work with all of those manufacturers of those tests to say we can help boost the benefit that people get from using your test at home. A parent doesn't want to do a strep test just to see it's positive, to then have to go to the doctor and get another strep test to get the prescription. They want to do it all at home and we want to be there to facilitate that.

Matt Hittle: Exciting possibilities. Dr. Mina, thank you so much for joining us today.

Dr. Michael Mina: Absolutely, very happy to.

Matt Hittle: Dr. Mario, that was a fantastic episode. I learned a lot from Dr. Mina. I think that, again, there's a lot of promise in this technology.

Dr. Mario Ramirez: Absolutely. You know, Michael has been talking about testing and the need for more testing for several years now. And I think he brought a level of understanding to the discussion I hope a lot of our listeners really enjoyed.

Matt Hittle: Yeah. We'll have to check back in with him as time goes on to get some more pandemic updates, but in the meantime we're recording right before the holidays. And so we hope everybody has a safe and healthy holiday. This has been Matthew Hittle with Akin Gump.

Dr. Mario Ramirez: And I'm Dr. Mario Ramirez with Akin Gump.

Matt Hittle: Join us next time on the next edition of *OnAir: Health Care*.